

Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

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SCHOLARONE™ Manuscripts Title: Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

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This observational study was reported according to the STROBE statement.

Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

Abstract

Objective: To examine the long-term effectiveness of the volunteer-delivered CHIP intervention.

Design: Cohort study

Setting: Hawera, New Zealand

Participants: Of the total cohort of 284 individuals who self-selected to complete the CHIP lifestyle intervention between 2007 and 2009, 106 (age = 64.9±7.4 years, range 42-87 years; 35% males, 65% female) returned in 2012 for a complimentary follow-up health assessment (mean follow-up duration = 49.2+10.4 months).

Intervention: 30-day lifestyle modification program (diet, physical activity, substance use and stress management) delivered by volunteers in a community setting.

Main outcome measures: Changes in body mass index (BMI), systolic and diastolic blood pressure (SBP, DBP), fasting plasma glucose (FPG), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides (TG).

Results: After approximately 4 years, participants with elevated biometrics at program entry maintained significantly lowered BMI (-3.2%; 34.8±5.4 versus 33.7±5.3 kg/m², p=0.02), DBP (-9.4%; 89.1±4.1 versus 80.8±12.6 mmHg, p=0.005), TC (-5.5%; 6.1±0.7 versus 5.8±1.0 mmol/L, p=0.04) and TG (-27.5%; 2.4±0.8 versus 1.7±0.7 mmol/L, p=0.002). SBP, HDL, LDL and FPG were not significantly different from baseline. Participants with elevated baseline biometrics who reported being compliant to the lifestyle principles promoted in the intervention (N=71, 67%) recorded further reductions in BMI (-4.2%; 34.8±4.5 versus 33.4±4.8 kg/m², p=0.02), DBP (-13.3%; 88.3±3.2 versus 77.1±12.1 mmHg, p=0.005) and FPG (-10.4%; 7.0±1.5 versus 6.3±1.3 mmol/L, p=0.02).

Conclusions: Individuals who entered the CHIP lifestyle intervention with elevated risk factors were able to maintain improvements in most biometrics for more than three years. The results suggest that the community-based CHIP lifestyle intervention can be effective in the longer-term, even when delivered by volunteers.

Key words: lifestyle intervention, CHIP, chronic disease, community based, volunteer, long-term

Article Summary

Article focus:

- 1. Lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.
- 2. Lifestyle interventions for preventing and managing chronic diseases are perceived to be costly and to have limited usefulness for reducing chronic disease risk in the long-term.
- 3. The Complete Health Improvement Program (CHIP) has demonstrated significant short-term benefits for the management of a number of chronic diseases. The aim of this study is to examine the long-term effectiveness of the volunteer-delivered CHIP intervention.

Key messages:

- 1. The CHIP intervention allows an ad libitum eating pattern, emphasising consumption of plant-based, whole-foods, which, being high in bulk, are satiating, but not calorically dense.
- 2. Long-term reductions in chronic disease risk factors can be achieved through an intensive, professionally-developed lifestyle intervention delivered by volunteers.
- 3. The CHIP intervention is an inexpensive tool for addressing the global public health crisis of chronic disease, particularly when delivered by volunteers.

Strengths:

- 1. Long-term appraisal of a lifestyle intervention program.
- 2. This, longest-term appraisal of CHIP to date, compares favourably with other professionally delivered CHIP interventions, including a RCT
- 3. This study compares favourably with other professionally delivered non-CHIP lifestyle interventions e.g. Diabetes Prevention Program.

Limitations:

- 1. Small sample size
- 2. Possible selection bias in the follow-up group with 37% returning for long-term follow-up.
- 3. Compliance to lifestyle behaviours was inadequately measured.

Introduction

The burden of chronic diseases, including cardiovascular disease (CVD), diabetes and cancer, represents a major health challenge worldwide [1 2]. Deaths from chronic diseases are projected to increase by 15% by 2020 [1]. Unhealthy lifestyle is recognized as one of the major risk factors of chronic diseases [1] and lifestyle interventions have been shown to be efficacious for their primary, secondary and early tertiary prevention [3-8]. Consequentially, lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.

While the merits of lifestyle interventions for managing chronic diseases are acknowledged, concerns exist regarding recidivism and cost. Health behavior decay is commonly observed in weight loss interventions, with long-term adherence to dietary modifications typically only achieved by a small proportion of individuals [9 10]. Notwithstanding, the Diabetes Prevention Program has shown meaningful reductions in body mass for up to 10 years after program entry [11]. With regards to cost, lifestyle interventions are often resource intensive and hence expensive. Residential programs, while demonstrating a high level of efficacy in the short-term, are especially cost prohibitive for many individuals. However, an increasing number of community-based interventions are becoming available. Recently, an adaptation of the Diabetes Prevention Program, utilizing community-health workers in community settings, was shown to be effective in reducing and maintaining reductions in weight, waist circumference and various diabetes indices two years after program entry [12].

The Complete Health Improvement Program (CHIP) is an intensive, community based lifestyle intervention that has demonstrated significant short-term benefits for the management of a number of chronic diseases [13-16]. The CHIP intervention has been delivered by both health professionals [17 18] and trained volunteers [7 8]. The aim of this study was to examine the long-term effectiveness of volunteer-delivered CHIP interventions which can be facilitated inexpensively.

Methods

The study targeted a rural community in New Zealand where CHIP interventions have been delivered by a team of volunteers since 2007. The volunteers had undergone two days of training to develop group facilitation skills and then been equipped with the comprehensive CHIP resource package that included: a curriculum guide for program delivery, 16 pre-recorded educational lectures presented by qualified experts, a cookbook and participant textbook and journal. The role of the volunteer director was to organise and facilitate the proceedings of the group sessions, not to educate.

Participants who completed the intervention three or more years previously (N=284) were invited to participate in the study, which involved a complimentary follow-up medical assessment. Of these 284 individuals, 106 (age = 64.9±7.4 years, range 42-87 years) agreed to participate in the study (37%

response rate). These individuals had completed the CHIP intervention on average 49.2±10.4 months (range = 3-5 years) prior to follow-up.

The 30-day group-based CHIP intervention, previously described [7 8], had encouraged and supported the participants to move towards a low-fat, plant-based diet *ad libitum*, with emphasis on the whole-foods consumption of grains, legumes, fruits and vegetables. The program had also encouraged participants to engage in 30 minutes of moderate-intensity physical activity daily and practice stress management techniques. Following completion of the program, a monthly support group was offered to the participants, although it was not considered part of the intervention. The same team of volunteer facilitators had delivered all the CHIP interventions in a uniform manner, utilizing the program resources provided.

At program entry, program completion (30 days) and follow-up (approximately 4 years), the participants' height, weight and BP were taken, and fasting (12-hour) blood samples were collected by trained phlebotomists and analyzed by a local pathology laboratory. Blood samples were analyzed for TC, LDL, HDL, TG and FPG levels. At follow-up, participants were also asked to complete a questionnaire that assessed their compliance with lifestyle principles advocated by the CHIP intervention. Participants were also asked about their attendance at the post-intervention monthly support meetings.

The data were analyzed using IBM™ Statistics (version 19) and expressed as mean±standard deviation. The extent of changes (percent, and mean with 95% confidence intervals (CI)) from baseline to post-intervention (30 days) and follow-up (mean = 49 months) were assessed using Analysis of Variance (repeated measures). We have previously shown that participants who make the greatest improvements in their biometrics during the CHIP intervention are those with the highest baseline levels [7]. Hence, the participants were stratified by normal or elevated baseline biometric levels. Cut-points for the biometrics included in the Metabolic Syndrome assemblage, as described by Alberti, et al. [19], were used: raised blood pressure (systolic ≥130 mmHg and/or diastolic ≥ 85 mmHg), elevated FPG (≥5.5mmol/L), increased TG (≥1.7mmol/L), decreased HDL (<1.03mmol/L in males and <1.3mmol/L in females) and waist circumference indicative of central obesity. As waist circumference was not measured in this study, body mass index (BMI) >30 kg/m² was used as a surrogate, as suggested by the International Diabetes Federation (IDF, 2006). Cut-points for TC (\geq 5.2mmol/L) and LDL (\geq 2.6mmol/L), not part of the suite of Metabolic Syndrome risk factors, were taken from the National Cholesterol Education Program Adult Treatment Panel III guidelines [20]. Pearson's Chisquare test was used on all demographic data variables, in order to investigate trends between participants who returned for follow-up and those who did not. Independent t-tests were used to compare baseline biometrics. The relationships between nominal variables likely to be associated with CHIP compliance were examined using Spearman's rank-order correlation (ρ) with two-tailed tests of significance. Participants were asked to what extent they adopted the principles promoted in the CHIP intervention since completing the program and a dichotomous variable was created: compliant ("all" or "most of principles") and

non-compliant ("a few" or "none of principles"). For all analyses, results were considered significant at P < 0.05.

Results

Significant improvements in all biometrics were observed over the 30-day intervention for the 106 participants who returned for the follow-up assessment (Table 1), which is consistent with other studies of the 30-day effectiveness of the CHIP intervention [7 8]. However, the primary interest of this study was the longer-term sustainability.

Table 1 Changes in biometrics at completion of the 30-day CHIP intervention.

	N	Baseline	30 days	Mean change (95%	%
		Buscinic	o day o	CI)	change
Weight (kg)	106	83.42±17.05	79.63±15.93	-3.79 (-4.20 to -3.38)	-4.5**
BMI (kg/m^2)	106	30.07±5.57	28.72±5.28	-1.35 (-1.49 to -1.21)	-4.5**
SBP (mmHg)	106	130.32±13.05	123.00±11.42	-7.32 (-9.48 to -5.17)	-5.6**
DBP (mmHg)	106	76.92±10.30	73.41±10.47	-3.51 (-5.46 to -1.56)	-4.6*
TC (mmol/L)	106	5.35±1.04	4.33±0.99	-1.01 (-1.13 to -0.90)	-18.9**
HDL (mmol/L)	106	1.35 ± 0.32	1.23±0.28	-0.12 (-0.15 to -0.09)	-8.7**
LDL (mmol/L)	106	3.36±0.94	2.56±0.86	-0.80 (-0.90 to -0.70)	-23.7**
TG (mmol/L)	106	1.41±0.74	1.22±0.61	-0.18 (-0.29 to -0.08)	-13.1*
FPG (mmol/L)	106	5.72±1.07	5.36±0.65	-0.37 (-0.50 to -0.23)	-6.4**
**p<0.001. **p<0.05				<u>-</u>	

Table 2 Baseline characteristics of participants who attended follow-up and those who did not.

those who that he	Jt.			
		Attended	Did not attend	
Characteristic		follow-up (%)	follow-up (%)	p
Gender	Male	37 (35.2)	62 (34.6)	0.92
	Female	68 (64.8)	117 (65.4)	
Marital status	Single	3 (3.0)	13 (7.6)	0.18
	Married	90 (90)	136 (80.0)	
	Divorced	4 (4.0)	10 (5.9)	
	Widowed	3 (3.0)	11 (6.5)	
Age, mean (SD),	, years	60.58 (8.41)	58.35 (12.49)	0.07
Weight, mean (S	SD) kg	83.44 (17.13)	91.14 (19.17)	0.001
BMI, mean (SD)	, kg/m²	30.04 (5.58)	32.92 (6.56)	< 0.001
SBP, mean (SD),	, mmHg	130.26 (13.09)	132.92 (15.55)	0.14
DBP, mean (SD)	, mmHg	77.03 (10.28)	77.36 (11.34)	0.80
TC, mean (SD), i	mmol/l	5.35 (1.05)	5.27 (1.11)	0.52
LDL, mean (SD)	, mmol/l	3.37 (0.93)	3.26 (0.97)	0.35
HDL, mean (SD)	, mmol/l	1.34 (0.32)	1.26 ((0.34)	0.05
TG, mean (SD),	mmol/l	1.41 (0.74)	1.63 (0.84)	0.03
FPG, mean (SD)	, mmol/l	5.72 (1.08)	6.10 (1.86)	0.03

Table 2 shows baseline characteristics of participants who did and did not attend the 3-5 year follow-up testing. There were no significant differences between the participants who did and did not undergo the 3-5 year follow-up testing in

baseline age, gender, marital status, SBP, DBP, TC, LDL and HDL. Individuals who did not attend the follow-up had significantly higher BMI, TG and FPG at program entry. There were no differences between those who and who did not attend follow-up, in the amount of change experienced in any of the biometrics during the 30-day intervention, even for the biometrics that were different between the groups at baseline (BMI: 1.35 ± 0.77 kg/m² versus 1.35 ± 0.72 kg/m², p=1.00; TG: 0.16 ± 0.64 mmol/L versus 0.19 ± 0.56 mmol/L, p=0.71; FPG: 0.55 ± 1.49 mmol/L versus 0.36 ± 0.70 mmol/L, p=0.23).

Of the 106 individuals who attended the follow-up, no significant change in any biometric was found. However, when changes in the biometrics were examined by baseline level of risk, significant decreases in several biometrics were observed (Table 3). Participants with elevated BMI, DBP, TC and TG at program entry had significantly lowered levels of these biometrics at the 49-month follow-up (Table 3). Conversely, follow-up levels of BP, LDL and FPG increased above baseline levels for participants who commenced the program with normal levels (Table 3).

Of the 106 CHIP participants who returned for follow-up assessments 71 (67%) reported being compliant to the lifestyle principles following completion of the 30-day program. Participants who reported being compliant were 2.8±5.8 kg (95% CI -4.48 to -1.11) (p<0.001) lighter at follow-up compared to program entry whereas the non-compliant participants had gained 1.8±7.0 kg (95% CI -1.27 to 4.82) (p=0.46), amounting to a change difference of almost 5 kg between the groups (p=0.001). The compliant and non-compliant groups were further analyzed according to baseline biometric risk levels (Table 4). Similar trends can be observed in Tables 3 and 4; however, compliant individuals who entered the program at elevated risk had even greater improvements in BMI, DBP and FPG (Table 4). Notably, compliant participants with elevated BMI at program entry weighed 4.9±7.2 kg (95% CI -8.10 to 1.62) less at the 3-5 year follow-up (p=0.002). Compliant participants with elevated baseline biometrics had significant reductions at follow-up for 3 of the 5 criteria for the Metabolic Syndrome. Conversely, compliant participants who commenced the program with normal baseline levels reported increases at follow-up in several biometrics (Table 4). Analyses of the non-compliant participants by baseline risk levels were not possible due to small numbers.

Post-intervention compliance was positively correlated with attendance at the monthly support meetings (ρ =0.402, p<0.001). Although only 26 of the study participants reported attending these meetings, all of these individuals reported being compliant to the lifestyle principles presented in the program. These individuals had a 3.5±4.8 kg (95% CI -5.95 to -1.12) (p=0.003) weight loss at follow-up but this was not significantly different (p=0.50) to the compliant individuals who did not attend the monthly support meetings (2.6±6.2 kg, 95% CI -4.92 to -0.24; p=0.03). While only few in number (N=13), participants who attended the support meetings and entered the program with elevated BMI had a highly significant weight loss at follow-up (5.6±5.3 kg, 95% CI -9.71 to -1.46; p=0.008). Yet this was once again not significantly different (p=0.82) to the

compliant individuals who entered the program with elevated BMI but did not attend the support meetings (N=18; 5.0±8.2 kg, 95% CI -10.11 to 0.11; p=0.06).

Attendance at monthly support meetings was not related to participating in the CHIP intervention with a spouse or friend (ρ =0.008, p=0.93): equal proportions of participants who attended with a partner either did or did not attend support meetings (69.2% versus 68.4%, p=0.93). Similarly, attending the CHIP intervention with a partner was not related to reported compliance at follow-up (p=0.17, p=0.08): there was no difference in the proportion of individuals who participated with a partner who reported being compliant or not compliant (73.2% versus 55.9%, p=0.08).

Table 3 Changes in highertrics at program	completion and 3-5 ve	are follow-up for part	cicipants with elevated baseline risk levels
rable 3 changes in biometrics at program	i completion and 3-3 yea	ais ionow-up for part	deligants with elevated baseline risk levels

Factor	JIIaI.	iges in biolii	eti ies at prog	Normal levels	ii aiia 5 5 yea	ars follow-up to	ı pa.	i cicipanto (vicii cicvatet	Elevated levels		
1 4001	N	Baseline	30 days	% change; mean	3-5 years	% change; mean	N	Baseline	30 days	% change; mean	3-5 years	% change; mean
I	14	Dascille	30 uays	change (95% CI)	follow-up	change (95%CI)	14	Dascille	30 uays	change (95%CI)	follow-up	change (95%CI)
BMI (kg/m²)	62	26.75±2.33	25.58±2.17	-4.4; -1.17 (-1.33	27.03±3.01	1.1; 0.28 (-0.34	44	34.75±5.44	33.15±5.20	-4.6; -1.60 (-1.93	33.65±5.28	-3.2; -1.10 (-2.04
(118/ 111 J	J <u>_</u>	20022.00	20.0022.17	to -1.02)**	203=0.01	to 0.90)		5 0=0.11	33.13-3.20	to -1.27)**	33.3323.20	to -0.16)*
SBP (mmHg)	46	119.04±8.06	117.89±10.91	-1.0; -1.15 (-4.82	129.67±14.23	8.9; 10.63 (5.38	60	138.97±8.8	126.92±10.27	-8.7; -12.05 (-	140.53±13.49	1.1; 1.57 (-3.04
(mm16)	10	117.01=0.00	1107_10.71	to 2.51)	127.07.211.20	to 15.89)**	33	4	1=0.75=10.57	15.14 to -8.96)**	110.00=10.17	to 6.17)
DBP (mmHg)	79	72.75±8.25	72.00±10.39	-1.0; -0.75 (-3.20	77.58±11.23	6.6; 4.84 (2.19 to	27	89.11±4.12	77.52±9.77	-13.0; -11.59 (-	80.78±12.55	-9.4; -8.33 (-
()				to 1.70)		7.48)**				16.15 to -7.03)**		14.40 to -2.27)*
TC (mmol/L)	48	4.41±0.52	3.60±0.64	-18.4; -0.81 (-	4.73±1.11	7.3; 0.32 (-0.03	58	6.12±0.66	4.94±0.80	-19.2; -1.18 (-	5.78±1.04	-5.5; -0.34 (-0.66
	-	- 	- -	0.98 to -0.65)**	- -	to 0.68)^	-		- 	1.39 to -0.97)**	* -	to -0.01)*
HDL (mmol/L)	72	1.50±0.27	1.34±0.25	-10.5; -0.16 (-	1.40±0.30	-6.7; -0.10 (-0.05	34	1.04±0.17	1.00±0.17	-3.4; -0.04 (-0.08	1.11±0.31	7.2; 0.07 (-0.01
/ -/			-	0.12 to -0.20) **		to -0.15)**		•		to 0.01)	-	to 0.16)
LDL (mmol/L)	20	2.07±0.50	1.50±0.40	-27.5; -0.57 (-	2.59±0.83	25.2; 0.52 (0.10	86	3.66±0.73	2.81±0.74	-23.2; -0.85 (-	3.58±0.96	-2.2; -0.08 (-0.32
. , ,				0.73 to -0.41)**		to 1.04)*		-		0.99 to -0.71)**		to 0.16)
TG (mmol/L)	80	1.09±0.32	1.05±0.37	-3.5; -0.04 (-0.11	1.19±0.56	9.6; 0.11 (-0.05	26	2.39±0.78	1.76±0.87	-26.5; -0.64 (-	1.73±0.72	-27.5; -0.66 (-
. , ,				to 0.04)*		to 0.26)				1.08 to -0.19)*		1.09 to -0.23)*
FPG (mmol/L)	66	5.17±0.29	5.06±0.30	-2.1; -0.11 (-0.21	5.29±0.40	2.4; 0.13 (0.03 to	40	6.64±1.26	5.85±0.76	-11.8; -0.79 (-	6.24±1.27	-6.0; -0.40 (-0.89
				to -0.01_*		0.22)*				1.14 to -0.43)**		to 0.10)
**p<0.001;	*p<0.	.05; ^p<0.1				0.22)*						

^{**}p<0.001; *p<0.05; ^p<0.1

Table 4 Changes in biometrics at program completion and 3-5 years follow-up by baseline level among self-reported compliant participants

			Normal						Elevated		
N	Baseline	30 days	% change; mean	3-5 years	% change; mean	N	Baseline	30 days	% change; mean	3-5 years	% change; mean
			change (95%CI)	follow-up	change (95%CI_				change (95%CI)	follow-up	change (95%CI)
39	26.51±2.50	25.33±2.34	-4.5; -1.18 (-1.40	26.22±2.75	-1.1; -0.29 (-0.92	32	34.82±4.54	33.29±4.24	-4.4; -1.53 (-1.92	33.35±4.77	-4.2; -1.47 (-2.67
			to -0.97**		to 0.24)				to -1.15**		to -0.27)*
35	119.00±8.78	116.94±11.65	-1.7; -2.06 (-6.58	127.91±12.91	7.5; 8.91 (3.54 to	36	138.50±8.39	127.33±9.09	-8.1; -11.17 (-	140.28±14.83	1.3; 1.78 (-4.74
			to 2.47)		14.29)*				14.79 to -7.55)**		to 8.29)
55	72.93±8.65	71.60±10.84	-1.8; -1.33 (-4.31	78.31±11.61		16	88.31±3.16	76.88±7.85	-13.0; -11.44 (-	77.13±12.13	-12.7; -11.19 (-
			to 1.66)		8.23)**				16.94 to -5.93)**		19.10 to -3.28)*
31	4.34±0.55	3.61±0.65	-16.9; -0.73 (-	4.65±1.07	7.1; 0.31 (-0.15 to	40	6.10±0.57	4.95±0.78	-18.8; -1.15 (-	5.78±0.95	-5.3; -0.33 (-0.69
			0.92 to -0.55)**		0.76)				1.40 to -0.90)**		to 0.04)^
51	1.51±0.26	1.35±0.23	-10.3; -0.16 (-	1.40±0.29	-7.4; -0.11 (-0.19	20	1.05±0.16	1.03±0.18	-2.3; -0.02 (-0.09	1.06±0.23	0.5; 0.01 (-0.09
			0.21 to -0.10)**		to -0.03)*				to 0.05)		to 0.10
15	2.03±0.57	1.45±0.44	-28.9; -0.59 (-	2.63±0.95	29.4; 0.60 (-0.10	56	3.68±0.67	2.89±0.72	-21.6; -0.80 (-	3.59±0.93	-2.5; -0.09 (-
			0.78 to -0.39)**		to 1.30)				0.96 to -0.63)**		0.36to 0.17)
52	1.03±0.32	0.99±0.31	-3.5; -0.04 (-0.13	1.13±0.62		19	2.33±0.80	1.69±0.88	-27.3; -0.64 (-	1.71±0.76	-26.8; -0.62 (-
									,		1.10 to -0.15_*
48	5.15±0.30	5.06±0.30	,	5.32±0.39		23	7.04±1.49	5.96±0.83		6.31±1.33	-10.4; -0.74 (-
			to 0.03)		0.28)*				1.62 to -0.55)**		1.36 to -0.11)*
o<0.c	/5; ^p<0.1										
	339 335 555 331 551 552 448	39 26.51±2.50 35 119.00±8.78 55 72.93±8.65 31 4.34±0.55 51 1.51±0.26 15 2.03±0.57 52 1.03±0.32	39 26.51±2.50 25.33±2.34 35 119.00±8.78 116.94±11.65 55 72.93±8.65 71.60±10.84 31 4.34±0.55 3.61±0.65 51 1.51±0.26 1.35±0.23 15 2.03±0.57 1.45±0.44 52 1.03±0.32 0.99±0.31 48 5.15±0.30 5.06±0.30	N Baseline 30 days % change; mean change (95%CI) 39 26.51±2.50 25.33±2.34 -4.5; -1.18 (-1.40 to -0.97** 35 119.00±8.78 116.94±11.65 -1.7; -2.06 (-6.58 to 2.47) 36 72.93±8.65 71.60±10.84 -1.8; -1.33 (-4.31 to 1.66) 31 4.34±0.55 3.61±0.65 -16.9; -0.73 (-0.92 to -0.55)** 31 1.51±0.26 1.35±0.23 -10.3; -0.16 (-0.21 to -0.10)** 31 2.03±0.57 1.45±0.44 -28.9; -0.59 (-0.78 to -0.39)** 32 1.03±0.32 0.99±0.31 -3.5; -0.04 (-0.13 to 0.06) 33 4.35; -0.16 (-0.23 to 0.03)	N Baseline 30 days % change; mean change (95%CI) follow-up (95%CI)	N Baseline 30 days % change; mean change (95%Cl) follow-up follow-up change (95%Cl_39 26.51±2.50 25.33±2.34 -4.5; -1.18 (-1.40 26.22±2.75 -1.1; -0.29 (-0.92 to -0.97** to 0.24) 35 119.00±8.78 116.94±11.65 -1.7; -2.06 (-6.58 127.91±12.91 7.5; 8.91 (3.54 to to 2.47) 14.29)* 55 72.93±8.65 71.60±10.84 -1.8; -1.33 (-4.31 78.31±11.61 7.4; 5.38 (2.53 to to 1.66) 8.23)** 31 4.34±0.55 3.61±0.65 -16.9; -0.73 (-4.65±1.07 7.1; 0.31 (-0.15 to 0.92 to -0.55)** 0.76) -7.4; -0.11 (-0.19 to -0.03)* 51 1.51±0.26 1.35±0.23 -10.3; -0.16 (-1.40±0.29 -7.4; -0.11 (-0.19 to -0.03)* 15 2.03±0.57 1.45±0.44 -28.9; -0.59 (-2.63±0.95 29.4; 0.60 (-0.10 to 1.30) 1.31±0.62 10.1; 0.10 (-0.12 to 0.06) 1.9; 0.10 (-0.23 5.32±0.39 3.3; 0.17 (0.05 to 0.05; ^p<0.15 (-1.9; 0.10 (-0.23 5.32±0.39 3.3; 0.17 (0.05 to 0.28)*	N Baseline 30 days % change; mean change (95%Cl) follow-up change (95%C	Baseline 30 days % change; mean change (95%CI) follow-up change (95%CI) N Baseline S 26.51±2.50 25.33±2.34 -4.5; -1.18 (-1.40 26.22±2.75 -1.1; -0.29 (-0.92 12.50 119.00±8.78 116.94±11.65 -1.7; -2.06 (-6.58 127.91±12.91 7.5; 8.91 (3.54 to 36 138.50±8.39 14.29)* 14.29)* 14.29)* 14.29)* 15.5 72.93±8.65 71.60±10.84 -1.8; -1.33 (-4.31 78.31±11.61 7.4; 5.38 (2.53 to 16 88.31±3.16 16.66) 8.23)** 1.51±0.26 1.35±0.23 -10.3; -0.16 (-0.21 to -0.10)** 1.51±0.26 1.35±0.23 -10.3; -0.16 (-0.21 to -0.10)** 1.45±0.44 -28.9; -0.59 (-0.21 to -0.39)** 1.45±0.44 -28.9; -0.59 (-0.39)** 1.03±0.32 1.03±0.32 0.99±0.31 -3.5; -0.04 (-0.13 1.13±0.62 10.1; 0.10 (-0.12 19 2.33±0.80 10.05; ^p=0.05; ^p=0.1 1.9±0.05; ^p=0.05; ^p=0.1 1.05±0.05; ^p=0.05; ^p=0.1 1.05±0.05; ^p=0.05; ^	Baseline 30 days % change; mean change (95%CI) follow-up change (95%CI) N Baseline 30 days 30 days 30 days Sample (95%CI) Sample (95%CI) Sa	N Baseline 30 days % change; mean change (95%CI) 610low-up 610low-	Saseline 30 days % change; mean change (95%CI) 30 days % change; mean change (95%CI) 610w-up 620w-up 620w-up

^{**}p<0.001; *p<0.05; ^p<0.1

Discussion

Substantial reductions in selected chronic disease risk factors were achieved within the 30-day CHIP lifestyle intervention, and importantly, the majority of these reductions were maintained three or more years among those participants who entered the program with elevated biometrics. These findings are particularly noteworthy as the intervention was administered by trained volunteers, which is a very cost-effective mode for delivering lifestyle interventions.

Strengths of this study and comparison with other studies

The 30-day results observed in this study are comparable to other studies of the CHIP intervention delivered by both health professionals and trained volunteers in the United States and Australasia [7 8 15]. Longer-term studies of participants in two professionally presented CHIP interventions have separately shown decreases in most biometrics at six and 12 months follow-up [17 18]. However, the present study is the longest-term appraisal of the CHIP intervention, and the only study of the sustainability of improvements achieved following participation in volunteer-delivered programs. The results in this study are similar in magnitude to those observed in a professionally-delivered randomized control trial in which the participants entered the program with much higher levels of BMI, DBP, TC, TG and FPG than the participants in this study[21].

The results of this study also compare favourably to other professionally delivered lifestyle interventions [22-24]. One of the goals of the Diabetes Prevention Program is for a reduction in body weight of at least 7% [25]. Participants in the present study with elevated FPG at program entry and who reported being compliant to the lifestyle principles presented in the CHIP intervention achieved a 5.2% reduction in body weight. This is a noteworthy outcome given that many of these participants did not receive ongoing support beyond the 30-day intervention. While ongoing support is recognized as important for minimizing health behavior decay and maintenance of long-term behavior change [26 27], these results suggest that even a short-lasting lifestyle intervention can have long-lasting benefits. It is also interesting that attending the post-intervention support meetings or participating in the CHIP intervention with a partner was not related to post-intervention compliance to the lifestyle principles presented in the program. Other researchers have found attending an intervention with a spouse or friend provides the greatest long-term weight loss [28 29]. The outcomes of this study may have been improved if all participants had engaged in ongoing support meetings. Even so, meaningful improvements in chronic disease risk factors can be achieved in some individuals without followup support. Strategies, however, for optimizing engagement in lifestyle interventions and increasing attendance at support meetings need to be explored further.

Factors contributing to the outcomes

One of the factors that may have contributed to the sustained outcomes observed in this study is the intensiveness of the intervention. With the intervention comprising 16 group sessions, CHIP is more intensive than most other community-based lifestyle interventions [11 30 31]. Studies of the long-term effectiveness of lifestyle interventions for reducing body weight, lipid levels, diabetes control and even the regression of atherosclerotic plaques, have shown a clear dose response [3 5 6 32]. However, other interventions in the literature are typically of three months duration, which may be more desirable for optimal long-term effects than the 30-day CHIP intervention [33]. Indeed, there is a need for further research to determine the most efficacious dosages of lifestyle interventions with regards to the number of sessions, program duration, and the type and magnitude of lifestyle modifications targeted. While cost was not a concern in this study as volunteers delivered the interventions, an understanding of dose response when applying lifestyle interventions will be an important consideration for making professionally delivered programs cost effective.

A second factor that may have contributed to the sustained weight loss observed in this study is the unique eating pattern advocated in the CHIP intervention. Most weight loss programs restrict energy intake by limiting portion sizes or food choices. However, this approach tends to result in hunger and dissatisfaction with the eating regime, which contributes to low compliance and weight regain [34-36]. Indeed, weight loss is rarely seen beyond two years of treatment [36 37]. The CHIP intervention allows an *ad libitum* eating pattern that emphasises the consumption of plant-based, whole-foods, which are high in bulk, and therefore satiating, yet by nature not calorically dense. This ad libitum eating pattern may be more acceptable to the participant than more restrictive diets. In fact, Barnard, et al. [38] reported similar levels of acceptability of plant-based diets to more traditional diets such as that recommended by the American Dietetic Association.

Long-term compliance to prescriptive regimes may also be more likely when participants enter a program with more adverse health parameters. Various studies have shown that patients with established disease are able to maintain high levels of adherence to intensive and prescriptive regimes [3 5 6 32 39]. Indeed, adherence to structured regimes has been shown to be more effective for weight loss than focusing on the macronutrient distribution [40 41]. In the present study, more promising outcomes were found among at-risk patients who reported being compliant to the CHIP lifestyle principles and entered the program with BMI indicative of obesity, and lipid and FPG profiles indicative of MetS. Likely, these individuals entered the program with an elevated readiness for change and hence willingness to engage in the intervention [42].

Limitations of the study

There are some limitations of this study that may have affected the observed results. Firstly, only 37% of participants accepted the invitation to attend the long-term follow-up assessment. While this represents a typical response rate [43], it is possible that the individuals who were more compliant to the lifestyle

principles presented in the intervention were more inclined to return for retesting, thereby biasing the outcomes. There were essentially no differences between those who did and did not return for the long-term follow up assessment in their biometrics at program entry or the outcomes achieved during the 30-day intervention, so these factors do not appear to account for the difference in response rate. It is likely that some of the participants who did not respond to the invitation were no longer residing in the area or were not available at the time of retesting. Nevertheless, even if the 71 participants who reported they were compliant comprised all the compliant individuals from the original sample of 284, this would still represent 25% of the original cohort. Hence, it is encouraging that between 25-70% of the individuals who participated in the CHIP intervention reported being compliant to the lifestyle principles promoted in the program on average 4 years after the 30-day intervention. Self-reported compliance was a further limitation of the study. As this was a subjective measure, variation in adherence to the CHIP lifestyle principles may have attenuated the long-term outcomes in the compliant group.

Lifestyle behaviours, such as dietary intake and physical activity, were also inadequately measured in the study. Therefore, it was not possible to determine the extent of changes in lifestyle behaviours the participants adopted during, and subsequent to, the 30-day intervention. Longitudinal studies need to collect comprehensive and validated lifestyle measurements and use these consistently throughout the duration of the study. Finally, the study only involved a small sample. Further investigation on a larger cohort it warranted.

Implications for public health and future directions

The novel finding of this study is that long-term reductions in chronic disease risk factors can be achieved through an intensive, professionally-developed lifestyle intervention delivered by volunteers. Harnessing the energy of volunteers to facilitate lifestyle interventions may provide a cost-effective mode for administering lifestyle interventions. A randomised control trial is needed to investigate the effectiveness and sustainability of the lifestyle choices acquired during the CHIP intervention and the associated long-term improvements in chronic disease risk factors. Further, this study needs to be replicated in a larger cohort and in other settings, to ascertain the generalisability of the study results.

Conclusions

The CHIP intervention can achieve significant reductions in chronic disease risk factors for more than three years after program entry. Further, when delivered by volunteers, the CHIP intervention is an inexpensive tool for addressing the public health crisis of chronic disease that threatens societies, communities, families and individuals. Further study of the long-term effectiveness of the CHIP intervention in other cultural settings is warranted.

Contributors:

HD developed the CHIP intervention. TH was involved in the facilitation of the original intervention. All authors were involved in the conception and design of

this study. TH and AH sought funding for this study. AH and PR applied for ethics approval. LK conducted the data analyses and LK, DM and PR were involved in interpretation of the analyses. LK and DM drafted the manuscript, and all authors critically revised it for intellectual content. All authors approved the final version to be published. LK is the guarantor.

Competing interests:

I/We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work except for AH who had financial support from Taranki Medical Foundation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Ethical approval: Consent for the study was obtained from New Zealand Health and Disability Upper South B Regional Ethics Committee, Ethics reference: URB/11/09/035.

Data sharing: no additional data available

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STROBE Statement—checklist of items included in reports of observational studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Cohort study included in the title	1
		(b) Summary of what was done and what was found included in abstract	1
Introduction			
Background/rationale	2	Scientific background and rationale for the investigation being reported included	2
Objectives	3	Objectives of study included	2
Methods			
Study design	4	Key elements of study design included early in the paper	2
Setting	5	The setting, locations, and relevant dates, including periods of recruitment,	2
		exposure, follow-up, and data collection were included	
Participants	6	(a) Cohort study— Selection of participants for intervention and follow-up methods included	2-3
		(b) Cohort study—Matching details not appropriate for this study	
Variables	7	All outcomes and their cut-points are described	3
Data sources/	8*	For each outcome variable, the sources of data and details of methods of	3
measurement		assessment (measurement) are described.	
Bias	9	Biases could not be controlled as this was a self-selected cohort, however, participant demographics were described in the manuscript.	4
Study size	10	Study size was not determined as all available data was included in the study	2-3
Quantitative variables	11	Explanation of how quantitative variables were handled in the analyses is provided.	3-4
		The selection of groupings and the rationale of this is described.	
Statistical methods	12	(a) All statistical methods used in the analysis are described	3-4
		(b) The methods used to examine subgroups is described	3-4
		(c) There was no missing data for the analyses of participants who attended follow-up	3, 7-8
		(d) Cohort study—Follow-up analysis was not part of the original intervention.	
		Additional funding was sought for this exercise and all participants who attended the o	riginal
		intervention were invited to attend the follow-up. Reasons for not responding to the inv	vitation
		were not sought.	
		(e) Comparison of baseline characteristics of those who attended follow-up and those who did not is provided in the manuscript.	4-5

Continued on next page

Results			
Participants	13*	(a) Numbers at each stage of the study are reported, including number in the intervention, returning for follow-up and in each subgroup analysed.	3, 7-8
		(b) Passans for not ottanding fallow, up were not assertained	
Dagarintiya	14*	(b) Reasons for not attending follow-up were not ascertained.(a) Characteristics of study participants (eg demographic, clinical, social) and information	4, 7-8
Descriptive data	14"	on outcomes provided	., , ,
uata		(b) Total number of participants as well as number for each variable of interest is provided	3, 7-8
		(c) Cohort study—follow-up time (eg, average and total amount) provided	3
		Cohort study—Numbers in subgroups for each outcome variables are provided for those who	7-8
Outcome data	15*	attended follow-up	7-0
Main results	16	(a) Changes in outcome variables over time including the precision (95% CI) are provided)	7-8
		(b) Category boundaries for continuous variables are documented	3
		(c) The reporting of absolute risk was not relevant	N/A
Other analyses	17	Analyses of subgroups was conducted showing interaction where this occurred	5-8
Discussion		A contract of the contract of	
	10	Key results with reference to study objectives were summarised	9
Key results	18	Limitations of the study, taking into account sources of potential bias or imprecision were	10
Limitations	19	discussed.	10
		A cautious overall interpretation of results, after considering results from similar studies,	11
Interpretation	20	limitations and other relevant evidence, was provided.	1.1
Generalisability	21	A comment regarding the generalisability of the results has been included in the discussion.	11
Other informati	on		
Funding	22	The source of funding for the study was provided	12
		2	



Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

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SCHOLARONE™ Manuscripts Title: Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

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This observational study was reported according to the STROBE statement.

Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

Abstract

Objective: To examine the long-term (three or more years) effectiveness of the volunteer-delivered CHIP intervention.

Design: Cohort study

Setting: Hawera, New Zealand

Participants: Of the total cohort of 284 individuals who self-selected to complete the CHIP lifestyle intervention between 2007 and 2009, 106 (37% of the original cohort, mean age = 64.9 ± 7.4 years, range 42-87 years; 35% males, 65% female) returned in 2012 for a complimentary follow-up health assessment (mean follow-up duration = 49.2 ± 10.4 months).

Intervention: 30-day lifestyle modification program (diet, physical activity, substance use and stress management) delivered by volunteers in a community setting.

Main outcome measures: Changes in body mass index (BMI), systolic and diastolic blood pressure (SBP, DBP), fasting plasma glucose (FPG), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides (TG).

Results: After approximately 4 years, participants with elevated biometrics at program entry maintained significantly lowered BMI (-3.2%; 34.8±5.4 versus 33.7±5.3 kg/m², p=0.02), DBP (-9.4%; 89.1±4.1 versus 80.8±12.6 mmHg, p=0.005), TC (-5.5%; 6.1±0.7 versus 5.8±1.0 mmol/L, p=0.04) and TG (-27.5%; 2.4±0.8 versus 1.7±0.7 mmol/L, p=0.002). SBP, HDL, LDL and FPG were not significantly different from baseline. Participants with elevated baseline biometrics who reported being compliant to the lifestyle principles promoted in the intervention (N=71, 67% of follow-up participants) recorded further reductions in BMI (-4.2%; 34.8±4.5 versus 33.4±4.8 kg/m², p=0.02), DBP (-13.3%; 88.3±3.2 versus 77.1±12.1 mmHg, p=0.005) and FPG (-10.4%; 7.0±1.5 versus 6.3±1.3 mmol/L, p=0.02).

Conclusions: Individuals who returned for follow-up assessment and entered the CHIP lifestyle intervention with elevated risk factors were able to maintain improvements in most biometrics for more than three years. The results suggest that the community-based CHIP lifestyle intervention can be effective in the longer-term, even when delivered by volunteers.

Key words: lifestyle intervention, CHIP, chronic disease, community based, volunteer, long-term

Article Summary

Article focus:

- 1. Lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.
- 2. Lifestyle interventions for preventing and managing chronic diseases are perceived to be costly and to have limited usefulness for reducing chronic disease risk in the long-term.
- 3. The Complete Health Improvement Program (CHIP) has demonstrated significant short-term benefits for the management of a number of chronic diseases. This study examined the long-term effectiveness of the volunteer-delivered CHIP intervention.

Key messages:

- 1. Long-term reductions in chronic disease risk factors were observed in the follow-up participants who had completed the volunteer-delivered CHIP intervention more than 3 years after program entry (mean duration = 49 months)...
- 2. The CHIP intervention is an inexpensive tool for addressing the global public health crisis of chronic disease, particularly when delivered by volunteers.

Strengths:

- 1. Long-term appraisal of a lifestyle intervention program.
- 2. This study compares favourably with other professionally delivered non-CHIP lifestyle interventions e.g. Diabetes Prevention Program.

Limitations:

- 1. Small sample size
- 2. Possible selection bias in the follow-up group with 37% returning for long-term follow-up.
- 3. Compliance to lifestyle behaviours was inadequately measured.

Introduction

The burden of chronic diseases, including cardiovascular disease (CVD), diabetes and cancer, represents a major health challenge worldwide [1 2]. Deaths from chronic diseases are projected to increase by 15% by 2020 [1]. Unhealthy lifestyle is recognized as one of the major risk factors of chronic diseases [1] and

lifestyle interventions have been shown to be efficacious for their primary, secondary and early tertiary prevention [3-8]. Consequentially, lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.

While the merits of lifestyle interventions for managing chronic diseases are acknowledged, concerns exist regarding recidivism and cost. Health behavior decay is commonly observed in weight loss interventions, with long-term adherence to dietary modifications typically only achieved by a small proportion of individuals [9 10]. Notwithstanding, the Diabetes Prevention Program has shown meaningful reductions in body mass for up to 10 years after program entry [11]. With regards to cost, lifestyle interventions are often resource intensive and hence expensive. Residential programs, while demonstrating a high level of efficacy in the short-term, are especially cost prohibitive for many individuals. However, an increasing number of community-based interventions are becoming available. Recently, an adaptation of the Diabetes Prevention Program, utilizing community-health workers in community settings, was shown to be effective in reducing and maintaining reductions in weight, waist circumference and various diabetes indices two years after program entry [12].

The Complete Health Improvement Program (CHIP) is an intensive, community based lifestyle intervention that has demonstrated significant short-term benefits for the management of a number of chronic diseases [13-16]. The CHIP intervention has been delivered by both health professionals [17 18] and trained volunteers [7 8]. The aim of this study was to examine the long-term effectiveness of volunteer-delivered CHIP interventions which can be facilitated inexpensively.

Methods

The study targeted a rural community in New Zealand where 30-day CHIP interventions have been delivered by a team of volunteers since 2007. The volunteers had undergone two days of training to develop group facilitation skills and then been equipped with the comprehensive CHIP resource package that included: a curriculum guide for program delivery, 16 pre-recorded educational lectures presented by qualified experts, a cookbook and participant textbook and journal. The role of the volunteer director was to organise and facilitate the proceedings of the group sessions, not to educate.

All 323 individuals, who had previously completed the CHIP intervention, were invited, by letter, to participate in a follow-up study, irrespective of their outcomes at 30 days. The letter included information detailing the intent of the study, as well as a complimentary follow-up medical assessment and a form for the participant to provide informed consent. Though the purpose of the study was to look at the long-term effects of the program (3+yrs) it was considered ethical to offer a follow-up health check to all the participants. Of the 192 that replied (59% response rate), 142 consented to participate; 50 did not. On the designated day for the study, 130 returned for the follow-up assessment. Of these 130 individuals, 106 (age = 64.9±7.4 years, range 42-87 years) who had

completed the intervention three or more years previously (mean = 49.2 ± 10.4 months, range = 3-5 years) were included in this study. As 284 of the original cohort of 323 participants had completed the intervention three or more years previously, the response rate for this study was 37%.

The 30-day group-based CHIP intervention, previously described [7 8], had encouraged and supported the participants to move towards a low-fat, plant-based diet *ad libitum*, with emphasis on the whole-foods consumption of grains, legumes, fruits and vegetables. The program had also encouraged participants to engage in 30 minutes of moderate-intensity physical activity daily and practice stress management techniques. Following completion of the program, a monthly support group was offered to the participants to reinforce lifestyle behaviour changes, and build a network of support and ongoing education, although it was not considered part of the intervention. The follow-up study was not planned at the time the participants enrolled in their respective CHIP programs and so participants were not advised of this eventuality. Invitations were extended to all participants to attend the follow-up study, regardless of whether or not they chose to attend the monthly support meetings. The same team of volunteer facilitators had delivered all the CHIP interventions in a uniform manner, utilising the program resources provided.

At program entry, 30 days and follow-up (approximately 4 years), the participants' height, weight and BP were taken by registered nurses, and fasting (12-hour) blood samples were collected by trained phlebotomists and analyzed by a local pathology laboratory. Blood samples were analysed for TC, LDL, HDL, TG and FPG levels. At follow-up, participants were also asked to complete a questionnaire that assessed their compliance with lifestyle principles advocated by the CHIP intervention. Participants were also asked about their attendance at the post-intervention monthly support meetings.

The data were analyzed using IBM™ Statistics (version 19) and expressed as mean±standard deviation. The extent of changes (percent, and mean with 95% confidence intervals (CI)) from baseline to post-intervention (30 days) and follow-up (mean = 49 months) were assessed using Analysis of Variance (repeated measures). We have previously shown that participants who make the greatest improvements in their biometrics during the CHIP intervention are those with the highest baseline levels [7]. Hence, the participants were stratified by normal or elevated baseline biometric levels. Cut-points for the biometrics included in the Metabolic Syndrome assemblage, as described by Alberti, et al. [19], were used: raised blood pressure (systolic ≥130 mmHg and/or diastolic ≥ 85 mmHg), elevated FPG (≥5.5mmol/L), increased TG (≥1.7mmol/L), decreased HDL (<1.03mmol/L in males and <1.3mmol/L in females) and waist circumference indicative of central obesity. As waist circumference was not measured in this study, body mass index (BMI) >30 kg/m² was used as a surrogate, as suggested by the International Diabetes Federation (IDF, 2006). Cut-points for TC (\geq 5.2mmol/L) and LDL (\geq 2.6mmol/L), not part of the suite of Metabolic Syndrome risk factors, were taken from the National Cholesterol Education Program Adult Treatment Panel III guidelines [20]. Pearson's Chisquare test was used on all demographic data variables, in order to investigate trends between participants who returned for follow-up and those who did not. Independent t-tests were used to compare baseline biometrics. The relationships between nominal variables likely to be associated with CHIP compliance were examined using Spearman's rank-order correlation (ρ) with two-tailed tests of significance. Participants were asked to what extent they adopted the principles promoted in the CHIP intervention since completing the program and a dichotomous variable was created: compliant ("all" or "most of principles") and non-compliant ("a few" or "none of principles"). For all analyses, results were considered significant at P < 0.05.

Results

Significant improvements in all biometrics were observed over the 30-day intervention for the 106 participants who returned for the follow-up assessment (Table 1), which is consistent with other studies of the 30-day effectiveness of the CHIP intervention [7 8]. However, the primary interest of this study was the longer-term sustainability. All biometrics significantly increased from program completion to follow-up (Table 1). However, weight was the only biometric in which a net improvement was sustained in the long-term. Participants were able to maintain an average 1.6% decrease in body weight over the long term compared to their weight at program entry. On the other hand, following program completion, SBP increased resulting in a net 4.2% increase from baseline to follow-up.

There were no significant differences between the participants who did and did not undergo the 3-5 year follow-up testing in baseline age (60.6 versus 58.4 years, p=0.07), gender (35.2% versus 34.6% men, p=0.92), marital status (90% versus 80% married, p=0.18), smoking status (70.3% versus 68.8%, p=0.28). Table 1 also shows baseline characteristics of participants who did and did not attend the 3-5 year follow-up testing. There were no significant differences between the participants who did and did not undergo follow-up testing in SBP, DBP, TC, LDL and HDL. Individuals who did not attend the follow-up had significantly higher BMI, TG and FPG at program entry. There were also no significant differences between those who did and who did not attend follow-up in 30-day levels of SBP, DBP, TC, LDL and FPG (Table 1). However, there were no significant differences in the amount of change experienced in any of the biometrics during the 30-day intervention, even for the biometrics that were different between the groups at baseline.

For all 106 individuals who attended the follow-up, no significant change in any biometric was found. However, when changes in the biometrics were examined by baseline level of risk, significant decreases in several biometrics were observed (Table 2). Participants with elevated BMI, DBP, TC and TG at program entry had significantly lowered levels of these biometrics at the 49-month follow-up (Table 2). Conversely, follow-up levels of BP, LDL and FPG increased above baseline levels for participants who commenced the program with normal levels (Table 2).

Of the 106 CHIP participants who returned for follow-up assessments 71 (67%) reported being compliant to the lifestyle principles following completion of the 30-day program. However, no compliance information was recorded for the original cohort who did not attend the follow-up assessment. Participants who reported being compliant were 2.8±5.8 kg (95% CI -4.48 to -1.11) (p<0.001) lighter at follow-up compared to program entry whereas the non-compliant participants had gained $1.8\pm7.0 \text{ kg}$ (95% CI -1.27 to 4.82) (p=0.46), amounting to a change difference of almost 5 kg between the groups (p=0.001). The compliant and non-compliant groups were further analyzed according to baseline biometric risk levels (Table 3). Similar trends can be observed in Tables 3 and 4; however, compliant individuals who entered the program at elevated risk had even greater improvements in BMI, DBP and FPG (Table 3). Notably, compliant participants with elevated BMI at program entry weighed 4.9±7.2 kg (95% CI -8.10 to 1.62) less at the 3-5 year follow-up (p=0.002). Compliant participants with elevated baseline biometrics had significant reductions at follow-up for 3 of the 5 criteria for the Metabolic Syndrome. Conversely, compliant participants who commenced the program with normal baseline levels reported increases at follow-up in several biometrics (Table 3). Analyses of the non-compliant participants by baseline risk levels were not possible due to small numbers.

Post-intervention compliance was positively correlated with attendance at the monthly support meetings (ρ =0.402, p<0.001). Although only 26 of the study participants reported attending these meetings, all of these individuals reported being compliant to the lifestyle principles presented in the program. These individuals had a 3.5±4.8 kg (95% CI -5.95 to -1.12) (p=0.003) weight loss at follow-up but this was not significantly different (p=0.50) to the compliant individuals who did not attend the monthly support meetings (2.6±6.2 kg, 95% CI -4.92 to -0.24; p=0.03). While only few in number (N=13), participants who attended the support meetings and entered the program with elevated BMI had a highly significant weight loss at follow-up (5.6±5.3 kg, 95% CI -9.71 to -1.46; p=0.008). Yet this was once again not significantly different (p=0.82) to the compliant individuals who entered the program with elevated BMI but did not attend the support meetings (N=18; 5.0±8.2 kg, 95% CI -10.11 to 0.11; p=0.06).

Attendance at monthly support meetings was not related to participating in the CHIP intervention with a spouse or friend (ρ =0.008, p=0.93): equal proportions of participants who attended with a partner either did or did not attend support meetings (69.2% versus 68.4%, p=0.93). Similarly, attending the CHIP intervention with a partner was not related to reported compliance at follow-up (ρ =0.17, p=0.08): there was no difference in the proportion of individuals who participated with a partner who reported being compliant or not compliant (73.2% versus 55.9%, p=0.08).

Table 1 Baselin	e biometrics and	changes	from baseline for	or participants w	ho attended long-term fo	llow-up (r	=106) and thos	e who did not (n=178)
Biometric	Attendance at	N	Baseline	30 days	Mean change 30 days	%	3-5 years	Mean change 3-5
	follow-up				(95% CI)	change	follow-up	years (95% CI)
Weight (kg)	Attended	106	83.42±17.05	79.63±15.93	-3.79 (-4.20 to -3.38)	-4.5**	82.12±16.17	-1.30 (-2.84 to 0.24)
	Did not attend	178	91.14±19.1†	87.36±18.18 ^{‡‡}	-3.78§ (-4.12 to -3.44)	-4.1**		
BMI (kg/m²)	Attended	106	30.07±5.57	28.72±5.28	-1.35 (-1.49 to -1.21)	-4.5**	29.78±5.24	-0.29 (-0.84 to 0.25)
	Did not attend	178	32.92±6.56††	31.57±6.30 ^{‡‡}	-1.35§ (-1.47 to -1.24)	-4.1**		
SBP (mmHg)	Attended	106	130.32±13.05	123.00±11.42	-7.32 (-9.48 to -5.17)	-5.6**	135.82±14.98	5.50 (1.95 to 9.05)
	Did not attend	178	132.92±15.55	125.98±13.88	-6.94§ (-9.82 to -5.05)	-5.2**		
DBP (mmHg)	Attended	106	76.92±10.30	73.41±10.47	-3.51 (-5.46 to -1.56)	-4.6*	78.40±11.60	1.48 (-0.79 to 3.76)
	Did not attend	178	77.36±11.34	73.04±10.45	-4.32§ (-5.81 to -2.83)	-5.6**		
TC (mmol/L)	Attended	106	5.35±1.04	4.33±0.99	-1.01 (-1.13 to -0.90)	-18.9**	5.31±1.19	-0.04 (-0.29 to 0.21)
	Did not attend	178	5.27±1.11	4.31±1.01	-0.96§ (-1.05 to -0.86)	-18.2**		
HDL (mmol/L)	Attended	106	1.35±0.32	1.23±0.28	-0.12 (-0.15 to -0.09)	-8.7**	1.31±0.33	-0.04 (-0.10 to 0.10)
	Did not attend	178	1.26±0.34	1.13±0.28‡	-0.13§ (-0.16 to -0.11)	-10.3**		
LDL (mmol/L)	Attended	106	3.36±0.94	2.56±0.86	-0.80 (-0.90 to -0.70)	-23.7**	3.39±1.01	0.03 (-0.19 to 0.26)
	Did not attend	178	3.26±0.97	2.51±0.85	-0.75§ (-0.83 to -0.66)	-23.0**		
TG (mmol/L)	Attended	106	1.41±0.74	1.22±0.61	-0.18 (-0.29 to -0.08)	-13.1*	1.32±0.64	-0.08 (-0.25 to 0.09)
	Did not attend	178	1.63±0.84 [†]	1.47±0.66‡	-0.16§ (-0.25 to -0.06)	-9.8*		
FPG (mmol/L)	Attended	106	5.72±1.07	5.36±0.65	-0.37 (-0.50 to -0.23)	-6.4**	5.65±0.95	-0.07 (-0.27 to 0.13)
, ,	Did not attend	178	6.10±1.86 [†]	5.55±1.10	-0.55§ (-0.77 to -0.33)	-9.0**		

†† difference in baseline between those who attended follow-up and those who did not at p<0.001 level of significance; † difference in baseline between those who attended follow-up and those who did not at p<0.05 level of significance; ‡ difference at 30 days between those who attended follow-up and those who did not at p<0.001 level of significance; ‡ difference at 30 days between those who attended follow-up and those who did not at p<0.05 level of significance; § difference in amount of change between those who attended follow-up and those who did not at p>0.05 level of significance; ** p<0.001; *p<0.05; ¹ % change from baseline

Table 2 Changes in biometrics at baseline, 30 days and 3-5 years follow-up for participants by baseline risk levels (n=106)										
Factor	Risk level	N	Baseline	30 days	% change; mean change (95% CI)	3-5 years follow-up	% change; mean change (95%CI)			
BMI	≤30 kg/m ²	62	26.75±2.33	25.58±2.17	-4.4; -1.17 (-1.33 to -1.02)**	27.03±3.01	1.1; 0.28 (-0.34 to 0.90)			
	>30 kg/m ²	44	34.75±5.44	33.15±5.20	-4.6; -1.60 (-1.93 to -1.27)**	33.65±5.28	-3.2; -1.10 (-2.04 to -0.16)			
SBP	<130mmHg	46	119.04±8.06	117.89±10.91	-1.0; -1.15 (-4.82 to 2.51)	129.67±14.23	8.9; 10.63 (5.38 to 15.89)*			
	≥130 mmHg	60	138.97±8.84	126.92±10.27	-8.7; -12.05 (-15.14 to -8.96)**	140.53±13.49	1.1; 1.57 (-3.04 to 6.17)			
DBP	<85mmHg	79	72.75±8.25	72.00±10.39	-1.0; -0.75 (-3.20 to 1.70)	77.58±11.23	6.6; 4.84 (2.19 to 7.48)**			
	≥ 85mmHg	27	89.11±4.12	77.52±9.77	-13.0; -11.59 (- 16.15 to -7.03)**	80.78±12.55	-9.4; -8.33 (-14.40 to -2.27			
TC	<5.2mmol/L	48	4.41±0.52	3.60±0.64	-18.4; -0.81 (-0.98 to -0.65)**	4.73±1.11	7.3; 0.32 (-0.03 to 0.68)^			
	(≥5.2mmol/L	58	6.12±0.66	4.94±0.80	-19.2; -1.18 (-1.39 to -0.97)**	5.78±1.04	-5.5; -0.34 (-0.66 to -0.01)			
HDL	≥1.03mmol/L (males);	72	1.50±0.27	1.34±0.25	-10.5; -0.16 (-0.12 to -0.20) **	1.40±0.30	-6.7; -0.10 (-0.05 to -0.15)			
	≥1.3mmol/L (females)									
	<1.03mmol/L (males);	34	1.04±0.17	1.00±0.17	-3.4; -0.04 (-0.08 to 0.01)	1.11±0.31	7.2; 0.07 (-0.01 to 0.16)			
	<1.3mmol/L (females)									
LDL	<2.6mmol/L	20	2.07±0.50	1.50±0.40	-27.5; -0.57 (-0.73 to -0.41)**	2.59±0.83	25.2; 0.52 (0.10 to 1.04)*			
	≥2.6mmol/L	86	3.66±0.73	2.81±0.74	-23.2; -0.85 (-0.99 to -0.71)**	3.58±0.96	-2.2; -0.08 (-0.32 to 0.16)			
TG	<1.7mmol/L	80	1.09±0.32	1.05±0.37	-3.5; -0.04 (-0.11 to 0.04)*	1.19±0.56	9.6; 0.11 (-0.05 to 0.26)			
	≥1.7mmol/L	26	2.39±0.78	1.76±0.87	-26.5; -0.64 (-1.08 to -0.19)*	1.73±0.72	-27.5; -0.66 (-1.09 to -0.23			
FPG	<5.5mmol/L	66	5.17±0.29	5.06±0.30	-2.1; -0.11 (-0.21 to -0.01_*	5.29±0.40	2.4; 0.13 (0.03 to 0.22)*			
	≥5.5mmol/L	40	6.64±1.26	5.85±0.76	-11.8; -0.79 (-1.14 to -0.43)**	6.24±1.27	-6.0; -0.40 (-0.89 to 0.10)			

≥5.5mmol/L 301 **p<0.001; *p<0.05; ^p<0.1

Table 3 Changes in biometrics at baseline, 30 days and 3-5 years follow-up by baseline level among self-reported compliant participants (n=71)

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Risk level	N	Baseline	30 days	% change; mean change	3-5 years	% change; mean change
			<u> </u>	(95%CI)	follow-up	(95%CI)
≤30 kg/m ²	39	26.51±2.50	25.33±2.34	-4.5; -1.18 (-1.40 to -0.97**	26.22±2.75	-1.1; -0.29 (-0.92 to 0.24)
>30 kg/m ²	32	34.82±4.54	33.29±4.24	-4.4; -1.53 (-1.92 to -1.15**	33.35±4.77	-4.2; -1.47 (-2.67 to -0.27)*
<130mmHg	35	119.00±8.78	116.94±11.65	-1.7; -2.06 (-6.58 to 2.47)	127.91±12.91	7.5; 8.91 (3.54 to 14.29)*
≥130 mmHg	36	138.50±8.39	127.33±9.09	-8.1; -11.17 (-14.79 to -7.55)**	140.28±14.83	1.3; 1.78 (-4.74 to 8.29)
<85mmHg	55	72.93±8.65	71.60±10.84	-1.8; -1.33 (-4.31 to 1.66)	78.31±11.61	7.4; 5.38 (2.53 to 8.23)**
≥ 85mmHg	16	88.31±3.16	76.88±7.85	-13.0; -11.44 (-16.94 to -5.93)**	77.13±12.13	-12.7; -11.19 (-19.10 to -3.28
<5.2mmol/L	31	4.34±0.55	3.61±0.65	-16.9; -0.73 (-0.92 to -0.55)**	4.65±1.07	7.1; 0.31 (-0.15 to 0.76)
≥5.2mmol/L	40	6.10±0.57	4.95±0.78	-18.8; -1.15 (-1.40 to -0.90)**	5.78±0.95	-5.3; -0.33 (-0.69 to 0.04)^
≥1.03mmol/L (males);	51	1.51±0.26	1.35±0.23	-10.3; -0.16 (-0.21 to -0.10)**	1.40±0.29	-7.4; -0.11 (-0.19 to -0.03)*
≥1.3mmol/L (females)						
<1.03mmol/L (males);	20	1.05±0.16	1.03±0.18	-2.3; -0.02 (-0.09 to 0.05)	1.06±0.23	0.5; 0.01 (-0.09 to 0.10
<1.3mmol/L (females)						·
<2.6mmol/L	15	2.03±0.57	1.45±0.44	-28.9; -0.59 (-0.78 to -0.39)**	2.63±0.95	29.4; 0.60 (-0.10 to 1.30)
≥2.6mmol/L	56	3.68±0.67	2.89±0.72	-21.6; -0.80 (-0.96 to -0.63)**	3.59±0.93	-2.5; -0.09 (-0.36to 0.17)
<1.7mmol/L	52	1.03±0.32	0.99±0.31	-3.5; -0.04 (-0.13 to 0.06)	1.13±0.62	10.1; 0.10 (-0.12 to 0.32)
(≥1.7mmol/L	19	2.33±0.80	1.69±0.88	-27.3; -0.64 (-1.10 to -0.18)*	1.71±0.76	-26.8; -0.62 (-1.10 to -0.15*
<5.5mmol/L	48	5.15±0.30	5.06±0.30	-1.9; 0.10 (-0.23 to 0.03)	5.32±0.39	3.3; 0.17 (0.05 to 0.28)*
≥5.5mmol/L	23	7.04±1.49	5.96±0.83	-15.4; -1.09 (-1.62 to -0.55)**	6.31±1.33	-10.4; -0.74 (-1.36 to -0.11)*
	≤30 kg/m² >30 kg/m² <130mmHg ≥130 mmHg ≥85mmHg ≥85mmHg <5.2mmol/L ≥5.2mmol/L ≥1.03mmol/L (males); ≥1.3mmol/L (females) <1.03mmol/L (females) <1.3mmol/L (females) <1.7mmol/L ≥2.6mmol/L ≤2.6mmol/L <1.7mmol/L <5.5mmol/L	$ \leq 30 \text{ kg/m}^2 \qquad 39 \\ > 30 \text{ kg/m}^2 \qquad 32 \\ < 130 \text{ mmHg} \qquad 35 \\ \geq 130 \text{ mmHg} \qquad 36 \\ < 85 \text{mmHg} \qquad 55 \\ \geq 85 \text{mmHg} \qquad 16 \\ < 5.2 \text{mmol/L} \qquad 31 \\ \geq 5.2 \text{mmol/L} \qquad 40 \\ \geq 1.03 \text{mmol/L} \text{ (males);} \qquad 51 \\ \geq 1.3 \text{mmol/L} \text{ (females)} \\ < 1.03 \text{mmol/L} \text{ (females)} \\ < 1.03 \text{mmol/L} \text{ (females)} \\ < 1.03 \text{mmol/L} \text{ (females)} \\ < 1.7 \text{mmol/L} \text{ (females)} \\ < 2.6 \text{mmol/L} \qquad 56 \\ < 1.7 \text{mmol/L} \qquad 52 \\ (\geq 1.7 \text{mmol/L} \qquad 19 \\ < 5.5 \text{mmol/L} \qquad 48 \\ $	$ \leq 30 \text{ kg/m}^2 \qquad \qquad 39 \qquad 26.51 \pm 2.50 \\ > 30 \text{ kg/m}^2 \qquad \qquad 32 \qquad 34.82 \pm 4.54 \\ < 130 \text{mmHg} \qquad \qquad 35 \qquad 119.00 \pm 8.78 \\ \ge 130 \text{ mmHg} \qquad \qquad 36 \qquad 138.50 \pm 8.39 \\ < 85 \text{mmHg} \qquad \qquad 55 \qquad 72.93 \pm 8.65 \\ \ge 85 \text{mmHg} \qquad \qquad 16 \qquad 88.31 \pm 3.16 \\ < 5.2 \text{mmol/L} \qquad \qquad 31 \qquad 4.34 \pm 0.55 \\ \ge 5.2 \text{mmol/L} \qquad \qquad 40 \qquad 6.10 \pm 0.57 \\ \ge 1.03 \text{mmol/L (males)}; \qquad 51 \qquad 1.51 \pm 0.26 \\ < 1.3 \text{mmol/L (females)} \\ < 1.03 \text{mmol/L (females)} \\ < 1.3 \text{mmol/L (females)} \\ < 2.6 \text{mmol/L} \qquad 15 \qquad 2.03 \pm 0.57 \\ \ge 2.6 \text{mmol/L} \qquad 56 \qquad 3.68 \pm 0.67 \\ < 1.7 \text{mmol/L} \qquad 52 \qquad 1.03 \pm 0.32 \\ (\ge 1.7 \text{mmol/L} \qquad 19 \qquad 2.33 \pm 0.80 \\ < 5.5 \text{mmol/L} \qquad 48 \qquad 5.15 \pm 0.30 \\ $	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

Discussion

Substantial reductions in selected chronic disease risk factors were achieved within the 30-day CHIP lifestyle intervention, and importantly, the majority of these reductions were maintained three or more years among those participants who returned for follow-up assessment and entered the program with elevated biometrics. These findings are particularly noteworthy as the intervention was administered by trained volunteers, which is a very cost-effective mode for delivering lifestyle interventions.

Strengths of this study and comparison with other studies

The 30-day results observed in this study are comparable to other studies of the CHIP intervention delivered by both health professionals and trained volunteers in the United States and Australasia [7 8 15]. Longer-term studies of participants in two professionally presented CHIP interventions have separately shown decreases in most biometrics at six and 12 months follow-up [17 18]. However, the present study is the longest-term appraisal of the CHIP intervention, and the only study of the sustainability of improvements achieved following participation in volunteer-delivered programs. The results in this study are similar in magnitude to those observed in a professionally-delivered randomized control trial in which the participants entered the program with much higher levels of BMI, DBP, TC, TG and FPG than the participants in this study[21].

The results of this study also compare favourably to other professionally delivered lifestyle interventions [22-24]. One of the goals of the Diabetes Prevention Program is for a reduction in body weight of at least 7% [25]. Participants in the present study with elevated FPG at program entry and who reported being compliant to the lifestyle principles presented in the CHIP intervention achieved a 5.2% reduction in body weight. This is a noteworthy outcome given that many of these participants did not receive ongoing support beyond the 30-day intervention. While ongoing support is recognized as important for minimizing health behavior decay and maintenance of long-term behavior change [26 27], these results suggest that even a short-lasting lifestyle intervention can have long-lasting benefits. It is also interesting that attending the post-intervention support meetings or participating in the CHIP intervention with a partner was not related to post-intervention compliance to the lifestyle principles presented in the program. Other researchers have found attending an intervention with a spouse or friend provides the greatest long-term weight loss [28 29]. The outcomes of this study may have been improved if all participants had engaged in ongoing support meetings. Even so, meaningful improvements in chronic disease risk factors can be achieved in some individuals without followup support. Strategies, however, for optimizing engagement in lifestyle interventions and increasing attendance at support meetings need to be explored further.

Factors contributing to the outcomes

One of the factors that may have contributed to the sustained outcomes observed in this study is the intensiveness of the intervention. With the intervention comprising 16 group sessions, CHIP is more intensive than most other community-based lifestyle interventions [11 30 31]. Studies of the long-term effectiveness of lifestyle interventions for reducing body weight, lipid levels, diabetes control and even the regression of atherosclerotic plaques, have shown a clear dose response [3 5 6 32]. However, other interventions in the literature are typically of three months duration, which may be more desirable for optimal long-term effects than the 30-day CHIP intervention [33]. Indeed, there is a need for further research to determine the most efficacious dosages of lifestyle interventions with regards to the number of sessions, program duration, and the type and magnitude of lifestyle modifications targeted. While cost was not a concern in this study as volunteers delivered the interventions, an understanding of dose response when applying lifestyle interventions will be an important consideration for making professionally delivered programs cost effective.

A second factor that may have contributed to the sustained weight loss observed in this study is the unique eating pattern advocated in the CHIP intervention. Most weight loss programs restrict energy intake by limiting portion sizes or food choices. However, this approach tends to result in hunger and dissatisfaction with the eating regime, which contributes to low compliance and weight regain [34-36]. Indeed, weight loss is rarely seen beyond two years of treatment [36 37]. The CHIP intervention allows an *ad libitum* eating pattern that emphasises the consumption of plant-based, whole-foods, which are high in bulk, and therefore satiating, yet by nature not calorically dense. This ad libitum eating pattern may be more acceptable to the participant than more restrictive diets. In fact, Barnard, et al. [38] reported similar levels of acceptability of plant-based diets to more traditional diets such as that recommended by the American Dietetic Association.

Long-term compliance to prescriptive regimes may also be more likely when participants enter a program with more adverse health parameters. Various studies have shown that patients with established disease are able to maintain high levels of adherence to intensive and prescriptive regimes [3 5 6 32 39]. Indeed, adherence to structured regimes has been shown to be more effective for weight loss than focusing on the macronutrient distribution [40 41]. In the present study, more promising outcomes were found among at-risk patients who reported being compliant to the CHIP lifestyle principles and entered the program with BMI indicative of obesity, and lipid and FPG profiles indicative of MetS. Likely, these individuals entered the program with an elevated readiness for change and hence willingness to engage in the intervention [42].

Limitations of the study

There are some limitations of this study that may have affected the observed results. Firstly, only 37% of participants accepted the invitation to attend the long-term follow-up assessment. The results of this analysis are therefore applicable to those participants who attended the long-term assessment and are

not generalisable to the original cohort. While this represents a typical response rate for behavioural interventions [43], it is possible that the individuals who were more compliant to the lifestyle principles presented in the intervention were more inclined to return for retesting, thereby biasing the outcomes. There were essentially no differences between those who did and did not return for the long-term follow up assessment in their biometrics at program entry or the outcomes achieved during the 30-day intervention, so these factors do not appear to account for the difference in response rate. It is likely that some of the 121 participants who did not respond to the invitation could not be contacted as they were no longer residing in the area were not available at the time of retesting, or chose not to respond. Some of those choosing not to return may have done so because they had not been compliant to the CHIP principles. Nevertheless, even if the 71 participants who reported they were compliant comprised all the compliant individuals from the study sample of 284, this would still represent 25% of the original cohort. Hence, it is encouraging that between 25-70% of the individuals who participated in the CHIP intervention reported being compliant to the lifestyle principles promoted in the program on average 4 years after the 30-day intervention. Self-reported compliance was a further limitation of the study. As this was a subjective measure, variation in adherence to the CHIP lifestyle principles may have attenuated the long-term outcomes in the compliant group.

Lifestyle behaviours, such as dietary intake and physical activity, were also inadequately measured in the study. Therefore, it was not possible to determine the extent of changes in lifestyle behaviours the participants adopted during, and subsequent to, the 30-day intervention. Longitudinal studies need to collect comprehensive and validated lifestyle measurements and use these consistently throughout the duration of the study. Finally, the study only involved a small sample. Further investigation on a larger cohort it warranted.

Implications for public health and future directions

The novel finding of this study is that long-term reductions in chronic disease risk factors can be achieved through an intensive, professionally-developed lifestyle intervention delivered by volunteers. Harnessing the energy of volunteers to facilitate lifestyle interventions may provide a cost-effective mode for administering lifestyle interventions. A randomised control trial is needed to investigate the effectiveness and sustainability of the lifestyle choices acquired during the CHIP intervention and the associated long-term improvements in chronic disease risk factors. Further, this study needs to be replicated in a larger cohort and in other settings, to ascertain the generalisability of the study results.

Conclusions

The CHIP intervention can achieve significant reductions in chronic disease risk factors for more than three years after program entry. Further, when delivered by volunteers, the CHIP intervention is an inexpensive tool for addressing the public health crisis of chronic disease that threatens societies, communities,

families and individuals. Further study of the long-term effectiveness of the CHIP intervention in other cultural settings is warranted.

Contributors:

HD developed the CHIP intervention. TH was involved in the facilitation of the original intervention. All authors were involved in the conception and design of this study. TH and AH sought funding for this study. AH and PR applied for ethics approval. LK conducted the data analyses and LK, DM and PR were involved in interpretation of the analyses. LK and DM drafted the manuscript, and all authors critically revised it for intellectual content. All authors approved the final version to be published. LK is the guarantor.

Competing interests:

I/We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

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Data sharing: no additional data available

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STROBE Statement—checklist of items included in reports of observational studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Cohort study included in the title	1
		(b) Summary of what was done and what was found included in abstract	1
Introduction			
Background/rationale	2	Scientific background and rationale for the investigation being reported included	2
Objectives	3	Objectives of study included	2
Methods			
Study design	4	Key elements of study design included early in the paper	2
Setting	5	The setting, locations, and relevant dates, including periods of recruitment,	2
		exposure, follow-up, and data collection were included	
Participants	6	(a) Cohort study— Selection of participants for intervention and follow-up methods included	2-3
		(b) Cohort study—Matching details not appropriate for this study	
Variables	7	All outcomes and their cut-points are described	3
Data sources/	8*	For each outcome variable, the sources of data and details of methods of	3
measurement		assessment (measurement) are described.	
Bias	9	Biases could not be controlled as this was a self-selected cohort, however, participant demographics were described in the manuscript.	4
Study size	10	Study size was not determined as all available data was included in the study	2-3
Quantitative variables	11	Explanation of how quantitative variables were handled in the analyses is provided.	3-4
		The selection of groupings and the rationale of this is described.	
Statistical methods	12	(a) All statistical methods used in the analysis are described	3-4
		(b) The methods used to examine subgroups is described	3-4
		(c) There was no missing data for the analyses of participants who attended follow-up	3, 7-8
		(d) Cohort study—Follow-up analysis was not part of the original intervention.	
		Additional funding was sought for this exercise and all participants who attended the o	riginal
		intervention were invited to attend the follow-up. Reasons for not responding to the inv	vitation
		were not sought.	
		(e) Comparison of baseline characteristics of those who attended follow-up and those who did not is provided in the manuscript.	4-5

Continued on next page

Results			<u>_</u>
Participants	13*	(a) Numbers at each stage of the study are reported, including number in the intervention, returning for follow-up and in each subgroup analysed.	3, 7-8
		(b) Reasons for not attending follow-up were not ascertained.	
Descriptive	14*	(a) Characteristics of study participants (eg demographic, clinical, social) and information	4, 7-8
data		on outcomes provided	
		(b) Total number of participants as well as number for each variable of interest is provided	3, 7-8
		(c) Cohort study—follow-up time (eg, average and total amount) provided	3
Outcome data	15*	Cohort study—Numbers in subgroups for each outcome variables are provided for those who attended follow-up	7-8
Main results	16	(a) Changes in outcome variables over time including the precision (95% CI) are provided)	7-8
		(b) Category boundaries for continuous variables are documented	3
		(c) The reporting of absolute risk was not relevant	N/A
Other analyses	17	Analyses of subgroups was conducted showing interaction where this occurred	5-8
Discussion			
Key results	18	Key results with reference to study objectives were summarised	9
Limitations	19	Limitations of the study, taking into account sources of potential bias or imprecision were discussed.	10
Interpretation	20	A cautious overall interpretation of results, after considering results from similar studies, limitations and other relevant evidence, was provided.	11
Generalisability	21	A comment regarding the generalisability of the results has been included in the discussion.	11
Other informati	on		
Funding	22	The source of funding for the study was provided	12
		2	

Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study

Abstract

Objective: To examine the long-term (three or more years) effectiveness of the volunteer-delivered CHIP intervention.

10 Design: Cohort study

Setting: Hawera, New Zealand

Participants: Of the total cohort of 284 individuals who self-selected to complete the CHIP lifestyle intervention between 2007 and 2009, 106 ($\frac{37\%}{6}$ of the original cohort, mean age = 64.9 ± 7.4 years, range 42-87 years; 35% males, 65% female) returned in 2012 for a complimentary follow-up health assessment (mean follow-up duration = $\frac{49.2\pm10.4}{6}$ months).

Intervention: 30-day lifestyle modification program (diet, physical activity, substance use and stress management) delivered by volunteers in a community setting.

Main outcome measures: Changes in body mass index (BMI), systolic and diastolic blood pressure (SBP, DBP), fasting plasma glucose (FPG), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides (TG).

Results: After approximately 4 years, participants with elevated biometrics at program entry maintained significantly lowered BMI (-3.2%; 34.8 ± 5.4 versus 33.7 ± 5.3 kg/m², p=0.02), DBP (-9.4%; 89.1 ± 4.1 versus 80.8 ± 12.6 mmHg, p=0.005), TC (-5.5%; 6.1 ± 0.7 versus 5.8 ± 1.0 mmol/L, p=0.04) and TG (-27.5%; 2.4 ± 0.8 versus 1.7 ± 0.7 mmol/L, p=0.002). SBP, HDL, LDL and FPG were not significantly different from baseline. Participants with elevated baseline biometrics who reported being compliant to the lifestyle principles promoted in the intervention (N=71, 67% of follow-up participants) recorded further reductions in BMI (-4.2%; 34.8 ± 4.5 versus 33.4 ± 4.8 kg/m², p=0.02), DBP (-13.3%; 88.3 ± 3.2 versus 77.1 ± 12.1 mmHg, p=0.005) and FPG (-10.4%; 7.0 ± 1.5 versus 6.3 ± 1.3 mmol/L, p=0.02).

Conclusions: Individuals who <u>returned for follow-up assessment and</u> entered the CHIP lifestyle intervention with elevated risk factors were able to maintain improvements in most biometrics for more than three years. The results suggest that the community-based CHIP lifestyle intervention can be effective in the longer-term, even when delivered by volunteers.

Key words: lifestyle intervention, CHIP, chronic disease, community based, volunteer, long-term

Article Summary

Article focus:

- 1. Lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.
- 2. Lifestyle interventions for preventing and managing chronic diseases are perceived to be costly and to have limited usefulness for reducing chronic disease risk in the long-term.
- 3. The Complete Health Improvement Program (CHIP) has demonstrated significant short-term benefits for the management of a number of chronic diseases. The aim of tThis study is to examined the long-term effectiveness of the volunteer-delivered CHIP intervention.

Key messages:

- 1. The CHIP intervention allows an ad libitum eating pattern, emphasising consumption of plant-based, whole-foods, which, being high in bulk, are satiating, but not calorically dense.
- 2.1. Long-term reductions in chronic disease risk factors were observed in the follow-up participants who had completed the volunteer-delivered CHIP intervention more than 3 years after program entry (mean duration = 49 months).can be achieved through an intensive, professionally-developed lifestyle intervention delivered by volunteers.
- 3.2. The CHIP intervention is an inexpensive tool for addressing the global public health crisis of chronic disease, particularly when delivered by volunteers.

Strengths:

- 1. Long-term appraisal of a lifestyle intervention program.
- 2. This, longest-term appraisal of CHIP to date, compares favourably with other professionally delivered CHIP interventions, including a RCT
- 3.2. This study compares favourably with other professionally delivered non-CHIP lifestyle interventions e.g. Diabetes Prevention Program.

Limitations:

- 1. Small sample size
- 2. Possible selection bias in the follow-up group with 37% returning for long-term follow-up.
- 3. Compliance to lifestyle behaviours was inadequately measured.

Introduction

The burden of chronic diseases, including cardiovascular disease (CVD), diabetes and cancer, represents a major health challenge worldwide [12]. Deaths from chronic diseases are projected to increase by 15% by 2020 [1]. Unhealthy lifestyle is recognized as one of the major risk factors of chronic diseases [1] and lifestyle interventions have been shown to be efficacious for their primary, secondary and early tertiary prevention [3-8]. Consequentially, lifestyle interventions are attracting increasing attention for managing the burgeoning rise of chronic disease.

While the merits of lifestyle interventions for managing chronic diseases are acknowledged, concerns exist regarding recidivism and cost. Health behavior decay is commonly observed in weight loss interventions, with long-term adherence to dietary modifications typically only achieved by a small proportion of individuals [9 10]. Notwithstanding, the Diabetes Prevention Program has shown meaningful reductions in body mass for up to 10 years after program entry [11]. With regards to cost, lifestyle interventions are often resource intensive and hence expensive. Residential programs, while demonstrating a high level of efficacy in the short-term, are especially cost prohibitive for many individuals. However, an increasing number of community-based interventions are becoming available. Recently, an adaptation of the Diabetes Prevention Program, utilizing community-health workers in community settings, was shown to be effective in reducing and maintaining reductions in weight, waist circumference and various diabetes indices two years after program entry [12].

The Complete Health Improvement Program (CHIP) is an intensive, community based lifestyle intervention that has demonstrated significant short-term benefits for the management of a number of chronic diseases [13-16]. The CHIP intervention has been delivered by both health professionals [17 18] and trained volunteers [7 8]. The aim of this study was to examine the long-term effectiveness of volunteer-delivered CHIP interventions which can be facilitated inexpensively.

Methods

The study targeted a rural community in New Zealand where 30-day CHIP interventions have been delivered by a team of volunteers since 2007. The volunteers had undergone two days of training to develop group facilitation skills and then been equipped with the comprehensive CHIP resource package that included: a curriculum guide for program delivery, 16 pre-recorded educational lectures presented by qualified experts, a cookbook and participant textbook and journal. The role of the volunteer director was to organise and facilitate the proceedings of the group sessions, not to educate.

All 323 individuals, who had previously completed the CHIP intervention, were invited, by letter, to participate in a follow-up study, irrespective of their outcomes at 30 days. The letter included information detailing the intent of the

study, as well as a complimentary follow-up medical assessment and a form for the participant to provide informed consent. Though the purpose of the study was to look at the long-term effects of the program (3+yrs) it was considered ethical to offer a follow-up health check to all the participants. Of the 192 that replied (59% response rate), 142 consented to participate; 50 did not. On the designated day for the study, 130 returned for the follow-up assessment. Of these 130 individuals, 106 (age = 64.9 ± 7.4 years, range 42-87 years) who had completed the intervention three or more years previously (mean = 49.2 ± 10.4 months, range = 3-5 years) were included in this study. As 284 of the original cohort of 323 participants had completed the intervention three or more years previously, the response rate for this study was 37%.

Participants who completed the intervention three or more years previously (N=284) were invited to participate in the study, which involved a complimentary follow-up medical assessment. Of these 284 individuals, 106 (age = 64.9 ± 7.4 years, range 42-87 years) agreed to participate in the study (37% response rate). These individuals had completed the CHIP intervention on average 49.2 ± 10.4 months (range = 3-5 years) prior to follow-up.

The 30-day group-based CHIP intervention, previously described [7 8], had encouraged and supported the participants to move towards a low-fat, plant-based diet *ad libitum*, with emphasis on the whole-foods consumption of grains, legumes, fruits and vegetables. The program had also encouraged participants to engage in 30 minutes of moderate-intensity physical activity daily and practice stress management techniques. Following completion of the program, a monthly support group was offered to the participants to reinforce lifestyle behaviour changes, and build a network of support and ongoing education, although it was not considered part of the intervention. The follow-up study was not planned at the time the participants enrolled in their respective CHIP programs and so participants were not advised of this eventuality. Invitations were extended to all participants to attend the follow-up study, regardless of whether or not they chose to attend the monthly support meetings. The same team of volunteer facilitators had delivered all the CHIP interventions in a uniform manner, utilizging the program resources provided.

At program entry, program completion (30 days) and follow-up (approximately 4 years), the participants' height, weight and BP were taken by registered nurses, and fasting (12-hour) blood samples were collected by trained phlebotomists and analyzed by a local pathology laboratory. Blood samples were analyzed for TC, LDL, HDL, TG and FPG levels. At follow-up, participants were also asked to complete a questionnaire that assessed their compliance with lifestyle principles advocated by the CHIP intervention. Participants were also asked about their attendance at the post-intervention monthly support meetings.

The data were analyzed using IBM™ Statistics (version 19) and expressed as mean±standard deviation. The extent of changes (percent, and mean with 95% confidence intervals (CI)) from baseline to post-intervention (30 days) and follow-up (mean = 49 months) were assessed using Analysis of Variance (repeated measures). We have previously shown that participants who make the

greatest improvements in their biometrics during the CHIP intervention are those with the highest baseline levels [7]. Hence, the participants were stratified by normal or elevated baseline biometric levels. Cut-points for the biometrics included in the Metabolic Syndrome assemblage, as described by Alberti, et al. [19], were used: raised blood pressure (systolic ≥130 mmHg and/or diastolic ≥ 85 mmHg), elevated FPG (≥5.5mmol/L), increased TG (≥1.7mmol/L), decreased HDL (<1.03mmol/L in males and <1.3mmol/L in females) and waist circumference indicative of central obesity. As waist circumference was not measured in this study, body mass index (BMI) > 30 kg/m² was used as a surrogate, as suggested by the International Diabetes Federation (IDF, 2006). Cut-points for TC (\geq 5.2mmol/L) and LDL (\geq 2.6mmol/L), not part of the suite of Metabolic Syndrome risk factors, were taken from the National Cholesterol Education Program Adult Treatment Panel III guidelines [20]. Pearson's Chisquare test was used on all demographic data variables, in order to investigate trends between participants who returned for follow-up and those who did not. Independent t-tests were used to compare baseline biometrics. The relationships between nominal variables likely to be associated with CHIP compliance were examined using Spearman's rank-order correlation (ρ) with two-tailed tests of significance. Participants were asked to what extent they adopted the principles promoted in the CHIP intervention since completing the program and a dichotomous variable was created: compliant ("all" or "most of principles") and non-compliant ("a few" or "none of principles"). For all analyses, results were considered significant at P < 0.05.

Results

Significant improvements in all biometrics were observed over the 30-day intervention for the 106 participants who returned for the follow-up assessment (Table 1), which is consistent with other studies of the 30-day effectiveness of the CHIP intervention [7 8]. However, the primary interest of this study was the longer-term sustainability. All biometrics significantly increased from program completion to follow-up (Table 1). However, weight was the only biometric in which a net improvement was sustained in the long-term. Participants were able to maintain an average 1.6% decrease in body weight over the long term compared to their weight at program entry. On the other hand, following program completion, SBP increased resulting in a net 4.2% increase from baseline to follow-up.

Table 1 Changes in biometrics at completion of the 30-day CHIP intervention.

'	Ŋ	Baseline	30 days	Mean change (95%	%
				CI)	change
Weight (kg)	106	83.42±17.05	79.63±15.93	-3.79 (-4.20 to -3.38)	-4.5**
BMI (kg/m²)	106	30.07 ± 5.57	28.72±5.28	-1.35 (-1.49 to -1.21)	-4.5**
SBP (mmHg)	106	130.32±13.05	123.00±11.42	-7.32 (-9.48 to -5.17)	-5.6**
DBP (mmHg)	106	76.92±10.30	73.41±10.47	-3.51 (-5.46 to -1.56)	-4.6*
TC (mmol/L)	106	5.35±1.04	4.33±0.99	-1.01 (-1.13 to -0.90)	-18.9**
HDL (mmol/L)	106	1.35±0.32	1.23±0.28	-0.12 (-0.15 to -0.09)	-8.7**
LDL (mmol/L)	106	3.36±0.94	2.56±0.86	-0.80 (-0.90 to -0.70)	-23.7**
TG (mmol/L)	106	1.41±0.74	1.22±0.61	-0.18 (-0.29 to -0.08)	-13.1*

	FPG (mmol/	(L) 106 5	5.72±1.07 5.3	36±0.65 -0.37	' (-0.50 to -0.23)	-6.4**
236 237	**p<0.001, **p<	0.05			-	
238	Table 2 Base	eline charact	eristics of particip	ants who attended	l follow-up and	
239	those who d				1	
			Attended	Did not attend		
Ch	aracteristic		follow-up (%)	follow-up (%)	p	
Ge	nder	Male	37 (35.2)	62 (34.6)	0.92	
		Female	68 (64.8)	117 (65.4)		
Ma	rital status	Single	3 (3.0)	13 (7.6)	0.18	
		Married	90 (90)	136 (80.0)		
		Divorced	4 (4.0)	10 (5.9)		
		Widowed	3 (3.0)	11 (6.5)		
Ag	e , mean (SD), j	years	60.58 (8.41)	58.35 (12.49)	0.07	
₩e	eight, mean (S	D) kg	83.44 (17.13)	91.14 (19.17)	0.001	
BM	H , mean (SD),	kg/m²	30.04 (5.58)	32.92 (6.56)	<0.001	
SB	P , mean (SD),	mmHg	130.26 (13.09)	132.92 (15.55)	0.14	
DB	P, mean (SD),	mmHg	77.03 (10.28)	77.36 (11.34)	0.80	
	, mean (SD), n		5.35 (1.05)	5.27 (1.11)	0.52	
	L, mean (SD),		3.37 (0.93)	3.26 (0.97)	0.35	
	L, mean (SD),		1.34 (0.32)	1.26 ((0.34)	0.05	
	, mean (SD), n		1.41 (0.74)	1.63 (0.84)	0.03	
	G, mean (SD),		5.72 (1.08)	6.10 (1.86)	0.03	
240						

Table 2 shows baseline characteristics of participants who did and did not attend the 3-5 year follow-up testing. There were no significant differences between the participants who did and did not undergo the 3-5 year follow-up testing in baseline age <u>(60.6 versus 58.4 years, p=0.07)</u>, gender <u>(35.2% versus 34.6% men,</u> p=0.92), marital_status (90% versus 80% married, p=0.18), smoking status (70.3% versus 68.8%, p=0.28). Table 21 also shows baseline characteristics of participants who did and did not attend the 3-5 year follow-up testing. There were no significant differences between the participants who did and did not undergo follow-up testing in SBP, DBP, TC, LDL and HDL. Individuals who did not attend the follow-up had significantly higher BMI, TG and FPG at program entry. There were <u>also</u> no <u>significant</u> differences between those who <u>did</u> and who did not attend follow-up in 30-day levels of SBP, DBP, TC, LDL and FPG (Table 1). However, there were no significant, indifferences in the amount of change experienced in any of the biometrics during the 30-day intervention, even for the biometrics that were different between the groups at baseline (BMI: 1.35±0.77) kg/m^2 versus 1.35±0.72 kg/m², p=1.00; TG: 0.16±0.64 mmol/L versus 0.19±0.56 mmol/L, p=0.71; FPG: 0.55±1.49 mmol/L versus 0.36±0.70 mmol/L, p=0.23).

Of the For all 106 individuals who attended the follow-up, no significant change in any biometric was found. However, when changes in the biometrics were examined by baseline level of risk, significant decreases in several biometrics were observed (Table 32). Participants with elevated BMI, DBP, TC and TG at

program entry had significantly lowered levels of these biometrics at the 49-month follow-up (Table 23). Conversely, follow-up levels of BP, LDL and FPG increased above baseline levels for participants who commenced the program with normal levels (Table 32).

Of the 106 CHIP participants who returned for follow-up assessments 71 (67%) reported being compliant to the lifestyle principles following completion of the 30-day program. However, no compliance information was recorded for the original cohort who did not attend the follow-up assessment. Participants who reported being compliant were 2.8±5.8 kg (95% CI -4.48 to -1.11) (p<0.001) lighter at follow-up compared to program entry whereas the non-compliant participants had gained $1.8\pm7.0 \text{ kg}$ (95% CI -1.27 to 4.82) (p=0.46), amounting to a change difference of almost 5 kg between the groups (p=0.001). The compliant and non-compliant groups were further analyzed according to baseline biometric risk levels (Table 43). Similar trends can be observed in Tables 3 and 4; however, compliant individuals who entered the program at elevated risk had even greater improvements in BMI, DBP and FPG (Table 43). Notably, compliant participants with elevated BMI at program entry weighed 4.9±7.2 kg (95% CI -8.10 to 1.62) less at the 3-5 year follow-up (p=0.002). Compliant participants with elevated baseline biometrics had significant reductions at follow-up for 3 of the 5 criteria for the Metabolic Syndrome. Conversely, compliant participants who commenced the program with normal baseline levels reported increases at follow-up in several biometrics (Table 43). Analyses of the non-compliant participants by baseline risk levels were not possible due to small numbers.

Post-intervention compliance was positively correlated with attendance at the monthly support meetings (p=0.402, p<0.001). Although only 26 of the study participants reported attending these meetings, all of these individuals reported being compliant to the lifestyle principles presented in the program. These individuals had a 3.5±4.8 kg (95% CI -5.95 to -1.12) (p=0.003) weight loss at follow-up but this was not significantly different (p=0.50) to the compliant individuals who did not attend the monthly support meetings (2.6±6.2 kg, 95% CI -4.92 to -0.24; p=0.03). While only few in number (N=13), participants who attended the support meetings and entered the program with elevated BMI had a highly significant weight loss at follow-up (5.6±5.3 kg, 95% CI -9.71 to -1.46; p=0.008). Yet this was once again not significantly different (p=0.82) to the compliant individuals who entered the program with elevated BMI but did not attend the support meetings (N=18; 5.0±8.2 kg, 95% CI -10.11 to 0.11; p=0.06).

Attendance at monthly support meetings was not related to participating in the CHIP intervention with a spouse or friend (p=0.008, p=0.93): equal proportions of participants who attended with a partner either did or did not attend support meetings (69.2% versus 68.4%, p=0.93). Similarly, attending the CHIP intervention with a partner was not related to reported compliance at follow-up (p=0.17, p=0.08): there was no difference in the proportion of individuals who participated with a partner who reported being compliant or not compliant (73.2% versus 55.9%, p=0.08).

Table 1 Baselin	e biometrics and cl	hanges	from baseline f	or participants w	ho attended long-term fo	llow-up (r	n=106) and thos	e who did not (n=178)	
<u>Biometric</u>	Attendance at	<u>N</u>	<u>Baseline</u>	<u>30 days</u>	Mean change 30 days	<u>%</u>	<u>3-5 years</u>	Mean change 3-5	<u>%</u>
	follow-up				(95% CI)	<u>change</u>	follow-up	<u>years (95% CI)</u>	<u>change^l</u>
Weight (kg)	<u>Attended</u>	106	83.42±17.05	79.63±15.93	-3.79 (-4.20 to -3.38)	-4.5**	82.12±16.17	-1.30 (-2.84 to 0.24)	<u>-1.6*</u>
	Did not attend	<u>178</u>	91.14±19.1 [†]	87.36±18.18 ^{‡‡}	-3.78§ (-4.12 to -3.44)	<u>-4.1**</u>			
BMI (kg/m ²)	<u>Attended</u>	<u>106</u>	30.07±5.57	28.72±5.28	-1.35 (-1.49 to -1.21)	-4.5**	29.78±5.24	-0.29 (-0.84 to 0.25)	<u>-1.0</u>
	Did not attend	<u>178</u>	32.92±6.56††	31.57±6.30 ^{‡‡}	-1.35§ (-1.47 to -1.24)	<u>-4.1**</u>			
SBP (mmHg)	<u>Attended</u>	<u>106</u>	130.32±13.05	123.00±11.42	-7.32 (-9.48 to -5.17)	-5.6**	135.82±14.98	5.50 (1.95 to 9.05)	4.2**
	Did not attend	<u>178</u>	132.92±15.55	125.98±13.88	-6.94§ (-9.82 to -5.05)	<u>-5.2**</u>			
DBP (mmHg)	<u>Attended</u>	<u>106</u>	76.92±10.30	73.41±10.47	-3.51 (-5.46 to -1.56)	-4.6*	78.40±11.60	1.48 (-0.79 to 3.76)	<u>1.9</u>
	<u>Did not attend</u>	<u>178</u>	77.36±11.34	73.04±10.45	-4.32§ (-5.81 to -2.83)	<u>-5.6**</u>			
TC (mmol/L)	<u>Attended</u>	<u>106</u>	5.35±1.04	4.33±0.99	-1.01 (-1.13 to -0.90)	<u>-18.9**</u>	5.31±1.19	-0.04 (-0.29 to 0.21)	<u>-0.7</u>
	Did not attend	<u>178</u>	5.27±1.11	4.31±1.01	-0.96§ (-1.05 to -0.86)	<u>-18.2**</u>			
HDL (mmol/L)	<u>Attended</u>	<u>106</u>	1.35±0.32	1.23±0.28	-0.12 (-0.15 to -0.09)	-8.7**	1.31±0.33	-0.04 (-0.10 to 0.10)	<u>-3.3</u>
	Did not attend	<u>178</u>	1.26±0.34	1.13±0.28‡	-0.13§ (-0.16 to -0.11)	-10.3**			
LDL (mmol/L)	<u>Attended</u>	<u>106</u>	3.36±0.94	2.56±0.86	-0.80 (-0.90 to -0.70)	-23.7**	3.39±1.01	0.03 (-0.19 to 0.26)	<u>1.0</u>
	Did not attend	<u>178</u>	3.26±0.97	2.51±0.85	-0.75§ (-0.83 to -0.66)	-23.0**			
TG (mmol/L)	<u>Attended</u>	<u>106</u>	1.41±0.74	1.22±0.61	-0.18 (-0.29 to -0.08)	-13.1*	1.32±0.64	-0.08 (-0.25 to 0.09)	<u>-5.9</u>
l <u></u>	Did not attend	<u>178</u>	1.63±0.84 [†]	1.47±0.66‡	-0.16§ (-0.25 to -0.06)	<u>-9.8*</u>			
FPG (mmol/L)	<u>Attended</u>	<u>106</u>	5.72±1.07	5.36±0.65	-0.37 (-0.50 to -0.23)	-6.4**	5.65±0.95	-0.07 (-0.27 to 0.13)	<u>-1.3</u>
11.1:00	Did not attend	<u>178</u>	6.10±1.86 [†]	<u>5.55±1.10</u>	-0.55§ (-0.77 to -0.33)	<u>-9.0**</u>			

†† difference in baseline between those who attended follow-up and those who did not at p<0.001 level of significance; † difference in baseline between those who attended follow-up and those who did not at p<0.05 level of significance; ‡ difference at 30 days between those who attended follow-up and those who did not at p<0.05 level of significance; ‡ difference at 30 days between those who attended follow-up and those who did not at p<0.05 level of significance; \$ difference in amount of change between those who attended follow-up and those who did not at p>0.05 level of significance; \$ p<0.05; \$ change from baseline

Table 32 Changes in biometrics at program completion and 3-5 years baseline, 30 days and 3-5 years follow-up for participants with

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322 elevated	<mark>by</mark> baseline risk levels <u> (n</u>	=106)					
<u>Factor</u>	<u>Risk level</u>	N	Baseline	30 days	% change; mean change	3-5 years	% change; mean change
•					(95% CI)	follow-up	(95%CI)
BMI	<u>≤30 kg/m²</u>	62	26.75±2.33	25.58±2.17	-4.4; -1.17 (-1.33 to -1.02)**	27.03±3.01	1.1; 0.28 (-0.34 to 0.90)
(kg/m²)	$>30 \text{ kg/m}^2$	<u>44</u>	34.75±5.44	33.15±5.20	-4.6; -1.60 (-1.93 to -1.27)**	33.65±5.28	-3.2; -1.10 (-2.04 to -0.16)*
SBP	<130mmHg	46	119.04±8.06	117.89±10.91	-1.0; -1.15 (-4.82 to 2.51)	129.67±14.23	8.9; 10.63 (5.38 to 15.89)**
(mmHg)	≥130 mmHg	<u>60</u>	138.97±8.84	126.92±10.27	-8.7; -12.05 (-15.14 to -8.96)**	140.53±13.49	1.1; 1.57 (-3.04 to 6.17)
DBP	<85mmHg	79	72.75±8.25	72.00±10.39	-1.0; -0.75 (-3.20 to 1.70)	77.58±11.23	6.6; 4.84 (2.19 to 7.48)**
(mmHg)	≥ 85mmHg	<u>27</u>	89.11±4.12	77.52±9.77	-13.0; -11.59 (- 16.15 to -7.03)**	80.78±12.55	-9.4; -8.33 (-14.40 to -2.27)*
TC	<5.2mmol/L	48	4.41±0.52	3.60±0.64	-18.4; -0.81 (-0.98 to -0.65)**	4.73±1.11	7.3; 0.32 (-0.03 to 0.68)^
(mmol/L)	(≥5.2mmol/L	<u>58</u>	6.12±0.66	4.94±0.80	-19.2; -1.18 (-1.39 to -0.97)**	5.78±1.04	-5.5; -0.34 (-0.66 to -0.01)*
HDL	≥1.03mmol/L (males);	72	1.50±0.27	1.34±0.25	-10.5; -0.16 (-0.12 to -0.20) **	1.40±0.30	-6.7; -0.10 (-0.05 to -0.15)**
(mmol/L)	≥1.3mmol/L (females)						
	<1.03mmol/L (males);	<u>34</u>	1.04±0.17	1.00±0.17	-3.4; -0.04 (-0.08 to 0.01)	1.11±0.31	7.2; 0.07 (-0.01 to 0.16)
	<1.3mmol/L (females)						
LDL	<2.6mmol/L	20	2.07±0.50	1.50±0.40	-27.5; -0.57 (-0.73 to -0.41)**	2.59±0.83	25.2; 0.52 (0.10 to 1.04)*
(mmol/L)	<u>≥2.6mmol/L</u>	<u>86</u>	3.66±0.73	2.81±0.74	-23.2; -0.85 (-0.99 to -0.71)**	3.58±0.96	-2.2; -0.08 (-0.32 to 0.16)
TG	<1.7mmol/L	80	1.09±0.32	1.05±0.37	-3.5; -0.04 (-0.11 to 0.04)*	1.19±0.56	9.6; 0.11 (-0.05 to 0.26)
(mmol/L)	<u>≥1.7mmol/L</u>	<u>26</u>	2.39±0.78	1.76±0.87	-26.5; -0.64 (-1.08 to -0.19)*	1.73±0.72	-27.5; -0.66 (-1.09 to -0.23)*
FPG	<u><5.5mmol/L</u>	_66_	5.17±0.29	5.06±0.30	-2.1; -0.11 (-0.21 to -0.01_*	5.29±0.40	2.4; 0.13 (0.03 to Formatted: Highligh
(mmol/L)	<u>≥5.5mmol/L</u>	<u>40</u>	6.64±1.26	5.85±0.76	-11.8; -0.79 (-1.14 to -0.43)**	6.24±1.27	-6.0; -0.40 (-0.89 to 0.10)
323 **p<0.001; *	*p<0.05; ^p<0.1						

330	Table 43 Changes in biometrics at program completion baseline, 30 days and 3-5 years follow-up by baseline level among self-reported
331	compliant participants (n=71)

	p						
<u>Factor</u>	<u>Risk level</u>	N	Baseline	30 days	% change; mean change	3-5 years	% change; mean change
•					(95%CI)	follow-up	(95%CI)
BMI	<u>≤30 kg/m²</u>	39	26.51±2.50	25.33±2.34	-4.5; -1.18 (-1.40 to -0.97**	26.22±2.75	-1.1; -0.29 (-0.92 to 0.24)
(kg/m²)	>30 kg/m ²	<u>32</u>	34.82±4.54	33.29±4.24	-4.4; -1.53 (-1.92 to -1.15**	33.35±4.77	-4.2; -1.47 (-2.67 to -0.27)*
SBP	<130mmHg	35	119.00±8.78	116.94±11.65	-1.7; -2.06 (-6.58 to 2.47)	127.91±12.91	7.5; 8.91 (3.54 to 14.29)*
(mmHg)	≥130 mmHg	<u>36</u>	138.50±8.39	127.33±9.09	-8.1; -11.17 (-14.79 to -7.55)**	140.28±14.83	1.3; 1.78 (-4.74 to 8.29)
DBP	<u><85mmHg</u>	55	72.93±8.65	71.60±10.84	-1.8; -1.33 (-4.31 to 1.66)	78.31±11.61	7.4; 5.38 (2.53 to 8.23)**
(mmHg)	≥ 85mmHg	<u>16</u>	88.31±3.16	76.88±7.85	-13.0; -11.44 (-16.94 to -5.93)**	77.13±12.13	-12.7; -11.19 (-19.10 to -3.28)*
TC	<5.2mmol/L	31	4.34±0.55	3.61±0.65	-16.9; -0.73 (-0.92 to -0.55)**	4.65±1.07	7.1; 0.31 (-0.15 to 0.76)
(mmHg)	≥5.2mmol/L	<u>40</u>	6.10±0.57	4.95±0.78	-18.8; -1.15 (-1.40 to -0.90)**	5.78±0.95	-5.3; -0.33 (-0.69 to 0.04)^
HDL	≥1.03mmol/L (males);	51	1.51±0.26	1.35±0.23	-10.3; -0.16 (-0.21 to -0.10)**	1.40±0.29	-7.4; -0.11 (-0.19 to -0.03)*
(mmHg)	≥1.3mmol/L (females)						
	<1.03mmol/L (males);	<u>20</u>	1.05±0.16	1.03±0.18	-2.3; -0.02 (-0.09 to 0.05)	1.06±0.23	0.5; 0.01 (-0.09 to 0.10
	<1.3mmol/L (females)						
LDL	<2.6mmol/L	15	2.03±0.57	1.45±0.44	-28.9; -0.59 (-0.78 to -0.39)**	2.63±0.95	29.4; 0.60 (-0.10 to 1.30)
(mmHg)	≥2.6mmol/L	<u>56</u>	3.68±0.67	2.89±0.72	-21.6; -0.80 (-0.96 to -0.63)**	3.59±0.93	-2.5; -0.09 (-0.36to 0.17)
TG	<1.7mmol/L	52	1.03±0.32	0.99±0.31	-3.5; -0.04 (-0.13 to 0.06)	1.13±0.62	10.1; 0.10 (-0.12 to 0.32)
(mmHg)	<u>(≥1.7mmol/L</u>	<u>19</u>	2.33±0.80	1.69±0.88	-27.3; -0.64 (-1.10 to -0.18)*	1.71±0.76	-26.8; -0.62 (-1.10 to -0.15*
FPG	<u><5.5mmol/L</u>	48	5.15±0.30	5.06±0.30	-1.9; 0.10 (-0.23 to 0.03)	5.32±0.39	3.3; 0.17 (0.05 to 0.2 Formatted: Highline
(mmHg)	≥5.5mmol/L	<u>23</u>	7.04±1.49	5.96±0.83	-15.4; -1.09 (-1.62 to -0.55)**	6.31±1.33	-10.4; -0.74 (-1.36 to -0.11)*

332 **p<0.001; *p<0.05; ^p<0.1

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Discussion

Substantial reductions in selected chronic disease risk factors were achieved within the 30-day CHIP lifestyle intervention, and importantly, the majority of these reductions were maintained three or more years among those participants who returned for follow-up assessment and entered the program with elevated biometrics. These findings are particularly noteworthy as the intervention was administered by trained volunteers, which is a very cost-effective mode for delivering lifestyle interventions.

Strengths of this study and comparison with other studies

The 30-day results observed in this study are comparable to other studies of the CHIP intervention delivered by both health professionals and trained volunteers in the United States and Australasia [7 8 15]. Longer-term studies of participants in two professionally presented CHIP interventions have separately shown decreases in most biometrics at six and 12 months follow-up [17 18]. However, the present study is the longest-term appraisal of the CHIP intervention, and the only study of the sustainability of improvements achieved following participation in volunteer-delivered programs. The results in this study are similar in magnitude to those observed in a professionally-delivered randomized control trial in which the participants entered the program with much higher levels of BMI, DBP, TC, TG and FPG than the participants in this study[21].

The results of this study also compare favourably to other professionally delivered lifestyle interventions [22-24]. One of the goals of the Diabetes Prevention Program is for a reduction in body weight of at least 7% [25]. Participants in the present study with elevated FPG at program entry and who reported being compliant to the lifestyle principles presented in the CHIP intervention achieved a 5.2% reduction in body weight. This is a noteworthy outcome given that many of these participants did not receive ongoing support beyond the 30-day intervention. While ongoing support is recognized as important for minimizing health behavior decay and maintenance of long-term behavior change [26 27], these results suggest that even a short-lasting lifestyle intervention can have long-lasting benefits. It is also interesting that attending the post-intervention support meetings or participating in the CHIP intervention with a partner was not related to post-intervention compliance to the lifestyle principles presented in the program. Other researchers have found attending an intervention with a spouse or friend provides the greatest long-term weight loss [28 29]. The outcomes of this study may have been improved if all participants had engaged in ongoing support meetings. Even so, meaningful improvements in chronic disease risk factors can be achieved in some individuals without followup support. Strategies, however, for optimizing engagement in lifestyle interventions and increasing attendance at support meetings need to be explored further.

Factors contributing to the outcomes

One of the factors that may have contributed to the sustained outcomes observed in this study is the intensiveness of the intervention. With the intervention comprising 16 group sessions, CHIP is more intensive than most other community-based lifestyle interventions [11 30 31]. Studies of the long-term effectiveness of lifestyle interventions for reducing body weight, lipid levels, diabetes control and even the regression of atherosclerotic plaques, have shown a clear dose response [3 5 6 32]. However, other interventions in the literature are typically of three months duration, which may be more desirable for optimal long-term effects than the 30-day CHIP intervention [33]. Indeed, there is a need for further research to determine the most efficacious dosages of lifestyle interventions with regards to the number of sessions, program duration, and the type and magnitude of lifestyle modifications targeted. While cost was not a concern in this study as volunteers delivered the interventions, an understanding of dose response when applying lifestyle interventions will be an important consideration for making professionally delivered programs cost effective.

A second factor that may have contributed to the sustained weight loss observed in this study is the unique eating pattern advocated in the CHIP intervention. Most weight loss programs restrict energy intake by limiting portion sizes or food choices. However, this approach tends to result in hunger and dissatisfaction with the eating regime, which contributes to low compliance and weight regain [34-36]. Indeed, weight loss is rarely seen beyond two years of treatment [36 37]. The CHIP intervention allows an *ad libitum* eating pattern that emphasises the consumption of plant-based, whole-foods, which are high in bulk, and therefore satiating, yet by nature not calorically dense. This ad libitum eating pattern may be more acceptable to the participant than more restrictive diets. In fact, Barnard, et al. [38] reported similar levels of acceptability of plant-based diets to more traditional diets such as that recommended by the American Dietetic Association.

Long-term compliance to prescriptive regimes may also be more likely when participants enter a program with more adverse health parameters. Various studies have shown that patients with established disease are able to maintain high levels of adherence to intensive and prescriptive regimes [3 5 6 32 39]. Indeed, adherence to structured regimes has been shown to be more effective for weight loss than focusing on the macronutrient distribution [40 41]. In the present study, more promising outcomes were found among at-risk patients who reported being compliant to the CHIP lifestyle principles and entered the program with BMI indicative of obesity, and lipid and FPG profiles indicative of MetS. Likely, these individuals entered the program with an elevated readiness for change and hence willingness to engage in the intervention [42].

Limitations of the study

There are some limitations of this study that may have affected the observed results. Firstly, only 37% of participants accepted the invitation to attend the long-term follow-up assessment. The results of this analysis are therefore applicable to those participants who attended the long-term assessment and are

not generalisable to the original cohort. While this represents a typical response rate for behavioural interventions [43], it is possible that the individuals who were more compliant to the lifestyle principles presented in the intervention were more inclined to return for retesting, thereby biasing the outcomes. There were essentially no differences between those who did and did not return for the long-term follow up assessment in their biometrics at program entry or the outcomes achieved during the 30-day intervention, so these factors do not appear to account for the difference in response rate. It is likely that some of the 121 participants who did not respond to the invitation could not be contacted as they were no longer residing in the area or were not available at the time of retesting, or chose not to respond. Some of those choosing not to return may have done so because they had not been compliant to the CHIP principles. Nevertheless, even if the 71 participants who reported they were compliant comprised all the compliant individuals from the original study sample of 284, this would still represent 25% of the original cohort. Hence, it is encouraging that between 25-70% of the individuals who participated in the CHIP intervention reported being compliant to the lifestyle principles promoted in the program on average 4 years after the 30-day intervention. Self-reported compliance was a further limitation of the study. As this was a subjective measure, variation in adherence to the CHIP lifestyle principles may have attenuated the long-term outcomes in the compliant group.

Lifestyle behaviours, such as dietary intake and physical activity, were also inadequately measured in the study. Therefore, it was not possible to determine the extent of changes in lifestyle behaviours the participants adopted during, and subsequent to, the 30-day intervention. Longitudinal studies need to collect comprehensive and validated lifestyle measurements and use these consistently throughout the duration of the study. Finally, the study only involved a small sample. Further investigation on a larger cohort it warranted.

Implications for public health and future directions

The novel finding of this study is that long-term reductions in chronic disease risk factors can be achieved through an intensive, professionally-developed lifestyle intervention delivered by volunteers. Harnessing the energy of volunteers to facilitate lifestyle interventions may provide a cost-effective mode for administering lifestyle interventions. A randomised control trial is needed to investigate the effectiveness and sustainability of the lifestyle choices acquired during the CHIP intervention and the associated long-term improvements in chronic disease risk factors. Further, this study needs to be replicated in a larger cohort and in other settings, to ascertain the generalisability of the study results.

Conclusions

The CHIP intervention can achieve significant reductions in chronic disease risk factors for more than three years after program entry. Further, when delivered by volunteers, the CHIP intervention is an inexpensive tool for addressing the public health crisis of chronic disease that threatens societies, communities,

families and individuals. Further study of the long-term effectiveness of the CHIP intervention in other cultural settings is warranted.

Contributors:

HD developed the CHIP intervention. TH was involved in the facilitation of the original intervention. All authors were involved in the conception and design of this study. TH and AH sought funding for this study. AH and PR applied for ethics approval. LK conducted the data analyses and LK, DM and PR were involved in interpretation of the analyses. LK and DM drafted the manuscript, and all authors critically revised it for intellectual content. All authors approved the final version to be published. LK is the guarantor.

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I/We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

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